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# REVIEW OF THE ADMINISTRATION'S PESTICIDE POLICY

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Y 4. AG 8/1:103-44

Review of the Administration's Pest...

## HEARING

BEFORE THE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS  
AND NUTRITION

OF THE

COMMITTEE ON AGRICULTURE  
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

SEPTEMBER 22, 1993

Serial No. 103-44



JUN 28 1994

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# REVIEW OF THE ADMINISTRATION'S PESTICIDE POLICY

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WEDNESDAY, SEPTEMBER 22, 1993

HOUSE OF REPRESENTATIVES,  
SUBCOMMITTEE ON DEPARTMENT  
OPERATIONS AND NUTRITION,  
COMMITTEE ON AGRICULTURE,  
*Washington, DC.*

The subcommittee met, pursuant to call, at 10:05 a.m., in room 1300, Longworth House Office Building, Hon. Charles W. Stenholm (chairman of the subcommittee) presiding.

Present: Representatives Dooley, Inslee, English, McKinney, Bishop, Volkmer, Holden, Lambert, Smith of Oregon, Gunderson, Allard, Barrett, Boehner, Ewing, and Canady.

Also present: Representative E (Kika) de la Garza, chairman of the committee, and Representative Pat Roberts, ranking minority member of the committee.

Staff present: Joseph Muldoon, associate counsel; Gary R. Mitchell, minority staff director; William E. O'Conner, Jr., minority policy coordinator; John E. Hogan, minority counsel; Dale Moore, minority legislative coordinator; Glenda L. Temple, clerk; Stan Ray, Joe Dugan, Curt Mann, and Pete Thomson.

## OPENING STATEMENT OF HON. CHARLES W. STENHOLM, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. STENHOLM. This hearing will come to order.

It is a pleasure to have before this subcommittee the distinguished representatives of the three agencies responsible for administering our Nation's pesticide and food safety policies. We recognize and appreciate the diligent efforts of you and your respective agencies over the last several months, and are extremely encouraged that USDA, EPA, and FDA have been able to work together to produce a comprehensive and mutually supported proposal addressing our Nation's pesticide policy.

These are complex and controversial issues, and just as it has been difficult for you all to reach a consensus, so too will it be difficult for us in the Congress, and our respective constituencies, to reach a consensus. But we must try; and we must be successful. I am fearful of the consequences if we are not.

Let me remind our witnesses, however, that the Agriculture Committee's constituency has traditionally been the ever-shrinking community of those involved in bringing food and fiber to the rest of us. We think we have done a good job in providing the most abundant food supply, the best quality of food, the safest food sup-

ply, at the lowest cost of any other country in the world. That is not to say that we are not also extremely interested in, among other things, improvement in the areas of environmental and consumer issues.

Today's farmer and rancher is extremely sensitive to the concerns of the American public, especially the consumer. The producer knows that he or she is successful only to the extent that the consumer is satisfied. Our task, however, should be to ensure that these decisions are based on good science, not temporary emotional appeal.

We in the producing side must accept the responsibility of our actions, and we sincerely and conscientiously do. We should expect no less of those who constantly criticize, question, and plant the seeds of doubt and distrust in our food system. But our tradition on the Agriculture Committee is based on production agriculture.

I came to the Congress, in fact, as a farmer and rancher who thought that someone with an agricultural background could contribute in a positive way to this process. I say this simply to make the point that it is through these eyes that many on this committee will view and subsequently judge your proposal. Accordingly, insofar as the Agriculture Committee has a role in this process, so too does the farmer and rancher.

Let me say last I think it is extremely important that we in the Congress do not let your momentum fade, but rather, move expeditiously in addressing these issues. The status quo is not acceptable. Although we are blessed with and often take advantage of that tremendous and wholesome food supply, as I mentioned a moment ago, today's society demands and deserves an updated legal framework by which to regulate that food supply. And the producer needs that same legal framework. From improving efficiencies in the regulatory process to assuring consumers that there is no significant risk associated with our Nation's food and fiber, improvement can and should be made.

I am anxious to move swiftly, to work cooperatively with other committees of jurisdiction, the full Agriculture Committee and this administration, in bringing a measure of this nature to the floor of the House as soon as possible.

With that, let me say again, I am delighted to have each of you here this morning and the subcommittee looks forward to your testimony.

Mr. Gunderson.

#### **OPENING STATEMENT OF HON. STEVE GUNDERSON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WISCONSIN**

Mr. GUNDERSON. Thank very much, Mr. Chairman, and let me join you in welcoming our distinguished panel of guests this morning. I, as a Republican, want to commend them for the bold steps that I think they have tried to pursue in recent weeks to come to some kind of a concrete proposal in this area.

Those who have listened to me at these hearings on this issue know of my frustration over 13 years at doing nothing. If you have achieved a proposal where both the environmental community and the industry are mad at you, then probably you have indeed been

successful because you know how we on this subcommittee feel. No matter what we do, we seem to get both sides upset with us.

My concern, and I guess my bit of cynicism, however, is reminded by the fact that in the last administration the three agencies came up with a seven-point proposal and when there was a discussion of that seven-point proposal, it became so contentious that it was never developed into legislative form and submitted to Capitol Hill.

I am hopeful that the three of you and your agencies will at least take the next step and submit to us specific legislation. Because in the absence of that specific legislation, there is no doubt in my mind that everyone in this room and everyone in this country interested in this issue will define and interpret your proposal to meet their own goals, and we will be left in the same quagmire we are left in today.

So I look forward to working with you. I think you have taken the right first step. But we have a rocky road to follow and I think we are going to have to do it together and on a bipartisan basis.

Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Dooley.

#### **OPENING STATEMENT OF HON. CALVIN M. DOOLEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA**

Mr. DOOLEY. Thank you, Mr. Chairman.

And I, too, want to follow on the comments of Mr. Gunderson and certainly commend the administration for moving forward on this difficult issue. I hope that they will, though, continue to aggressively advance a proposal and provide the impetus to help us form legislation that can resolve this issue, both on behalf of the consumers and certainly the agricultural and the processing industry, which really needs some certainty that just does not exist at this time.

So with that, Mr. Chairman, I thank you for holding this hearing and look forward to hearing from the witnesses.

Mr. STENHOLM. Mr. Canady.

#### **OPENING STATEMENT OF HON. CHARLES T. CANADY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA**

Mr. CANADY. Thank you, Mr. Chairman.

I have a brief statement I would like to submit for the record. I would especially like to welcome Administrator Browner, my fellow Floridian, I am very pleased that she is here today. I look forward to her testimony.

The issues we are dealing with today are among the most important issues that this subcommittee deals with for Florida agriculture. These are absolutely critical for us, probably the most important issues other than the North American Free-Trade Agreement. I am pleased at some of the proposals the administration has advanced, particularly with respect to the Delaney clause. I think we are very encouraged by that.

We look forward to working with the administration on other aspects of this proposal.

Mr. STENHOLM. Without objection, your entire statement will be made a part of the record.

[The prepared statement of Mr. Canady follows:]

CHARLES T. CANADY  
12TH DISTRICT, FLORIDA

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DEPARTMENT OPERATIONS AND NUTRITION  
FOREIGN AGRICULTURE AND HUNGER

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THE HONORABLE CHARLES T. CANADY  
of Florida

before the House Agriculture Subcommittee on  
Department Operations and Nutrition

September 22, 1993

THANK YOU, MR. CHAIRMAN. I want to join with my colleagues in welcoming today's witnesses from the Administration. I also want to emphasize the concern that has been expressed by many members and agricultural producers over the past several years that we must improve the process by which pesticides and agricultural chemicals are registered and reregistered.

As we have seen in Florida over the past five years, safe, effective agricultural chemicals have been either cancelled or not reregistered at an alarming rate. This decline in available pesticides has greatly affected Florida's \$6.1 billion agricultural industry.

I am pleased to see that the Administration has taken a position that places the out-dated Delaney Clause where it belongs -- on the shelf. However, I am concerned with the vagueness of certain provisions in the Administration's proposal. I am curious to learn who is going to come up with a definition for "a reasonable certainly of no harm", a "significant disruption to domestic production" or "reasonably likely" -- to quote a few of the phrases that I understand are in this proposal. If these terms are not defined in a precise, scientific manner, I fear that we may end up doing more harm than good to the agricultural industry and to American consumers.

I am especially glad to see Administrator Browner with us today. Her knowledge and experience with Florida's agricultural industry will provide a useful base from which to view the special needs and concerns of the industry.

Mr. Chairman, we face a formidable challenge. Do we move forward in a manner that will allow America's farmers to continue their livelihood and still provide the American consumer a safe, abundant food supply at reasonable price levels? Or do we move toward a program that further restricts the ability of farmers to produce, that encourages foreign imports and that limits the availability of agricultural products for American families?

Mr. Chairman, I commend you and Mr. Smith for calling today's hearing and I look forward to the testimony of our witnesses.

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Mr. STENHOLM. Mr. English.

Mr. ENGLISH. Thank you, Mr. Chairman. I have no statement.

Mr. STENHOLM. Mr. Barrett.

Mr. BARRETT. Thank you, Mr. Chairman.

I, too, look forward to the testimony this morning from the Clinton administration pesticide policy proposal. I think we all seem to agree that our current policy is perhaps flawed and perhaps a little outdated, but unfortunately we may disagree on what reform should actually look like. So I appreciate the presence of the panel and I look forward to the testimony.

Thank you.

Mr. STENHOLM. Mr. Holden.

Mr. HOLDEN. Mr. Chairman, I commend you for holding this hearing today.

During my first 9 months in office, I have heard repeatedly from my farmers that we need a sensible pesticide policy in this country. I also look forward to the presentation that the administration is going to make today. I think that we are in the right step and we are moving forward, and I welcome the opportunity to hear the testimony.

Thank you.

Mr. STENHOLM. Mr. Roberts.

#### **OPENING STATEMENT OF HON. PAT ROBERTS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KANSAS**

Mr. ROBERTS. Thank you, Mr. Chairman.

You and I have been either driving the stagecoach or riding shotgun on this FIFRA beast now for about 144 months, as I recall, and we have tried mightily to at least get on the animal for 8 seconds, get some kind of an award. And it has been very difficult.

Yesterday I appeared before the all powerful Energy and Commerce Committee on behalf of the sometimes powerful House Agriculture Committee, in an effort to really emphasize to Chairman Waxman and to Senator Kennedy and to others, more especially Mr. Bliley and Mr. Lehman, our firm willingness to try to get a solution to this.

Chairman Waxman indicated that it was a new book on pesticides and that we had an opportunity. I certainly think we do have an opportunity.

I want to associate myself with your remarks, more particularly to the fact that we do have the best quality food at the lowest price in the history of the world and we need to improve that, but we certainly don't need to do anything that would put the food supply at greater risk.

In the interest of time, I am not going to repeat that testimony, which should make the pending witnesses very happy, but I do have a statement in regards to the administration's proposal. And I am encouraged about the administration's proposal, more especially in regard to the obvious need to fix the Delaney clause. I said that over and over again in my statement yesterday.

I do have some concern when it comes to regulating farmers' access to newer and safer pesticides, which I think is absolutely crucial. I am looking forward to more detail on how the administration plans on treating benefits to society.

I don't have the proposal right in front of me, but yesterday when we gave it a first look or at least in terms of the members, I didn't find any reference to benefits. And I think that must be included, more especially from the use of newer and safer pesticides. So we will have to work with the Administrator in that regard.

In addition, I am concerned about the proposal that would penalize farmers and ranchers, Mr. Chairman, by canceling pesticides based on any kind of delay at the EPA and not sound science. And I am also eager to work with the administration's suggestion to require only farmers to keep records on the use of pesticides that have been certified by EPA as general-use pesticides and of little risk to the environment. I think that could be counter to Vice President Gore's proposal to reduce paperwork and to streamline Government.

Now, having listed at least three concerns with the administration's proposal, you will find that as the ranking minority member of the sometimes powerful House Agriculture Committee in charge of a semiwild and woolly 19-member posse of Republicans that we always smother the administration with the milk of human kindness. We will try to work with you, lest the milk tend to curdle with further delay. So we look forward to your testimony.

I have some questions of Secretary Rominger and we will proceed. I hope we can get some answers to this very difficult situation, Mr. Chairman.

Thank you for your time and bless you in your work as you go forth.

[The prepared statement of Mr. Roberts follows:]

The Honorable Pat Roberts  
 Hearing Statement before the  
 Subcommittee on Health and the Environment  
 Committee on Energy and Commerce  
 September 21, 1993

Chairman Waxman: Thank you for the opportunity to appear before your Subcommittee today to discuss the federal food safety policy.

Thank you also to my good friend from Virginia, Mr. Bliley, for his leadership on H.R. 1627, the "Food Quality Protection Act." This bill, with 120 cosponsors led by Messrs. Bliley, Lehman, Rowland, and Bob Smith, represents a solution to the vexing issue of food safety reform that is supported by virtually the entire agricultural industry.

For many years, members of the Agriculture Committee and the Energy and Commerce Committee have wrestled with the statutes within our respective jurisdictions that regulate the manufacture and use of pesticides to achieve some common sense, critically needed reforms.

Our efforts in the Agriculture Committee to improve the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and your Committee's efforts to reform the Federal Food, Drug, and Cosmetic Act (FFDCA) have been working toward the same general goal -- ensuring this country's agricultural industry continues to produce the safest, most abundant, most affordable food supply in the world.

We also have been running into the same general problem relative to a successful completion of our combined efforts -- the FFDCA's Section 409, otherwise known as the Delaney Clause. The paradox imposed by the Delaney Clause on federal pesticide regulatory policies -- that being the situation where a pest management product approved through FIFRA's rigorous registration and review procedures for use on a specific food commodity can be determined to be in violation of Delaney's zero-tolerance standard for that same commodity when processed -- has been discussed and cussed to the point that most everyone involved in the debate has everyone else's stump speeches on the issue memorized.

We all have been anxiously awaiting details from Clinton Administration officials on their solutions to resolving this conflict. The High Court has let stand the Ninth U.S. Circuit Court's ruling that effectively says EPA does not have the authority to regulate pesticide residues in processed foods at a negligible risk level. We have examined and debated the findings of the National Academy of Sciences report on the question of whether children's diets and physiology make them more or less at risk to possible pesticide exposure risks than the population in general.

Roberts, page two

Despite all this, it is interesting to note the debate, and the goal, have remained unchanged for several years. We need to fix Delaney. We need to authorize establishment of a flexible, scientifically valid risk assessment standard that:

- Protects against unreasonable risks for human health and the environment;
- Recognizes and considers the value, or benefits, the use of a particular pest control product provides consumers and the public in general;
- And, regulates the process in such a manner that ensures uniformity in the administration of federal food safety laws.

As I mentioned, everyone involved in food safety as it relates to regulating the use of pesticides has been anxious for the Administration to unveil its plan. Generally, the Roberts, E&C hearing, page three outline of the plan Administration officials have been discussing with Congress and the private sector are encouraging.

One might be so bold as to suggest the verbal descriptions of the Clinton food safety policy track closely with the reforms proposed for the FFDCA put forth in H.R. 1627. For example, I am encouraged that the Clinton plan does not propose codifying science into law, but instead supports using a more flexible, narrative standard for defining risk.

However, there are many details and unresolved issues relative to FFDCA reforms that must be addressed if there is to be any realistic chance of enacting reforms during the 103rd Congress. Some of the most troublesome gaps in our understanding of the details of the package surround the issue of benefits -- namely, will benefits be included; and if so, will they be subjected to some kind of phase-out timetable.

The consideration of benefits is important to the assessment of the relative safety of any pesticide, and must be part of the final reform package. I will not argue that the review of benefits data needs to consider issues beyond the basic economic impact on a farmer's or rancher's production. Just as with risk, the benefits of a particular pesticide can effect the public and the environment at many different levels.

For example, the benefits of a particular pesticide should include examination of those provided to consumers in terms of food cost and variety in the selection of foods available. If the loss of a particular pesticide would limit domestic production of certain fruits and vegetables, consumers would not only face higher costs, but lower-income consumers might be forced to omit these foods from their diets -- foods the National Academy of Sciences deems important in preventing cancer.

In addition, the possibility of establishing in law a set of arbitrary timetables to phase-out benefits makes no sense. A pesticide's benefits do not disappear with the turning of the calendar's pages. For the benefits of a particular pesticide to diminish or be eliminated would require:

Roberts, page three

- the disappearance of the pests for which the use of the pesticide is designed;
- or the development of newer, more effective (and affordable) pest control products and methods that are realistic alternatives for the pesticide in question -- and, that said alternatives are available to producers.

This last point -- availability -- is most critical. History suggests the time required to move a new pesticide product from its inception in the laboratory to commercial availability is approximately 10 years. If a currently registered product is saddled with a 5-year, or even a 10-year phase-out, producers could find themselves swatting at pests with the rolled-up promise of an alternative sometime down the road -- likely at a time when the producers are out of business.

Another concern is the issue of national uniformity. In addition to making sure the provisions of the two statutes work in uniform manner, there is a need to establish that issuing of tolerance limits on pesticide residues or other restrictions rests with the federal government. The broad issue of making the regulation of pesticides apply uniformly across the nation covers provisions in both FIFRA and FFDCA. Certainly the Agriculture Committee will be examining the uniformity provisions pertinent to FIFRA, so I will not take the Subcommittee's time today to review those in detail.

But with regard to FFDCA, let me point out that the rigors a pesticide is put through in the process of determining the maximum acceptable residue level involves the painstaking review by EPA scientists of literally millions of data endpoints. I do not know of any governmental body that is not facing a tight budget situation. Yet there are those who firmly believe every state or local government will have the resources to provide the depth of scientific analysis necessary to make valid decisions with any level of consistency and efficiency. I do not think that is a realistic scenario.

By the same token, those of us supporting H.R. 1627 recognize that in some instances, state agencies may be in a better position to assess specific local conditions that may warrant establishment of a different tolerance level, whether higher or lower. That is why our bill provides the framework for states to petition for a different tolerance or limit on the basis of compelling local conditions. The critical point regarding uniformity is that such an exception would be established by a review of the scientific evidence presented by the petitioner to ensure the exception remains consistent with the parameters and goals of federal food safety policies.

There are many more issues we could discuss this afternoon. But in the interest of time and recognizing the long road ahead of us in addressing these tough issues, let me conclude that I look forward to working with you to finalize a package of food safety policy reforms that serve the best interests of making certain we continue to provide American's a safe, wholesome and affordable supply of food and fiber products.

Mr. STENHOLM. The chairman appreciates very much the extremely temperate, kind, and succinct manner in which you have expressed your concerns and your praise for the proposal and the witnesses before us today.

Mr. ROBERTS. Did you understand anything this morning on that rural health care business? Can you help me with that?

Mr. STENHOLM. I understood very clearly. We will explain that to you at some later date.

Mr. ROBERTS. I appreciate it.

Mr. STENHOLM. Mr. Inslee.

Mr. INSLEE. I don't have anything, Mr. Chairman.

Mr. STENHOLM. Dr. Allard.

Mr. ALLARD. Thank you, Mr. Chairman. I don't have any comments.

Mr. STENHOLM. Mr. Boehner.

[No response.]

Mr. STENHOLM. Mr. Volkmer.

Mr. VOLKMER. I appreciate the chairman having the hearings, and look forward to the testimony.

Mr. STENHOLM. A couple of observations in light of the extreme kind and gentle remarks of the gentleman from Kansas. Perhaps the problem we have had is that we have not understood as clearly as Mr. Smith does that it is 8 seconds you have to stay on that critter. We have been trying to stay on for 10 seconds and we have not made it. So we have not been following the rules.

Mr. Smith.

## **OPENING STATEMENT OF HON. ROBERT F. (BOB) SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON**

Mr. SMITH of Oregon. Does that determine the length of my statement, Mr. Chairman?

Thank you very much, Mr. Chairman. I, too, wish to welcome Secretary Rominger, Administrator Browner, and Commissioner Kessler, and thank them for coming here today to outline the President's proposal.

I want to examine the President's proposal according to his own yardstick, putting people first. In other words, how will this proposal ensure that we have an adequate, wholesome, and economical food supply?

From what I currently understand about the administration's proposal, I am not sure how we can reach that goal at this time. I have been able to identify 10 major problems with the proposal, which I have outlined in my testimony. And I want to just discuss one or two quickly here.

Despite assurances that the consideration of benefits would play a prominent role in this legislation, I have yet to hear or see the word benefit in any of the administration's discussions. A new phaseout authority would allow the EPA to use an easier standard than cancellation procedures to gradually and effectively cancel use of chemicals based upon the rather dubious criteria of, "credible scientific evidence." I would find it difficult to seriously consider accepting legislation with so many faults.

However, this subcommittee is not without alternatives. H.R. 1627 currently enjoys 120 cosponsors, Republicans and Democrats, from the House Committee on Agriculture, from the House Committee on Energy and Commerce, and from the membership of the total House.

In addition, H.R. 1627 enjoys widespread support from the agricultural and food processing community, with endorsements from over 230 organizations.

H.R. 1627 would provide the EPA the regulatory authority needed to more quickly eliminate the use of pesticides under the cancellation process and remove time-consuming paperwork constraints that have in the past slowed EPA efforts to prohibit the use of pesticides in emergency situations.

Again, Mr. Chairman, I want to thank you for holding these hearings. I would like to meld the best of H.R. 1627 with the administration's proposals and see if we can indeed put people first.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Smith of Oregon follows:]

STATEMENT OF  
ROBERT F. SMITH  
BEFORE THE  
SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION  
SEPTEMBER 22, 1993

Mr. Chairman, I'd like to thank you for calling this hearing today. While this is not the premiere of the Administration's pesticide policy proposal, at least it's the first week of the run. I welcome Deputy Secretary Rominger, Administrator Browner, and Commissioner Kessler and thank them for coming here to outline President Clinton's proposal.

It has always been my view that government should not adopt a solely adversarial relationship with taxpayers. It has been my experience that the negative regulatory and enforcement functions are emphasized to the exclusion of all else and at the expense of the very taxpayers we were sent here to help.

I believe government should be an advocate of development, growth and prosperity for its citizens. The Department of Agriculture, the Food and Drug Administration, and the Environmental Protection Agency should be working to ensure that appropriate and safe pest control technologies are available for the benefit of producers, processors and consumers.

I will be examining the President's proposal according to his own yardstick: putting people first. In other words, how will this proposal ensure that we have an adequate, wholesome and economical food supply?

From what I currently understand about the Administration's proposal, I cannot imagine how it could achieve this goal. So far, I have been able to identify ten major problem areas with the proposal. Please allow me to summarize my concerns here.

Despite assurances that the consideration of benefits would play a prominent role, I have yet hear or see the word benefits in any of the Administration's discussions of the proposal. In its place are "time-limited transitional tolerances" of no more than five years if the loss of the pesticide would result in "significant disruption of food supply."

The consideration risks associated with pest control technologies would never be questioned because its good common sense. Though the techniques of risk assessment are evolutionary, complex and open to debate, we accept the challenge because we have no choice.

Benefits assessment is just as complex and challenging as risk assessment. To simplify the problem of pesticide regulation, many would have us dismiss benefits altogether, saying we should not be interested in the profits of farmers and chemical companies. Such a narrow benefits standard does an injustice to the nutritional welfare of consumers, the budgets of low income shoppers, and the economic well being of all in this nation involved in food production from farm to table.

The role of benefits in the regulation of pest controls should not be effectively eliminated in order to lighten the work of bureaucrats or to ease the agenda of environmental interest groups. I regret the Administration's decision to virtually ignore the role of benefits in risk assessment.

President Clinton has proposed a registration sunset in which pesticide registrations and tolerances would require renewal every 15 years. Data would have to be in by year 12, even if EPA decides a new, five year study is necessary in year eleven. This adds regulatory cost and additional economic risks to pest control methods and agricultural production.

A new phase-out authority would allow the EPA to use a easier standard than cancellation procedure to gradually and effectively cancel use of chemicals based on "credible scientific evidence". For my mind, a chemical is either safe or it is not, consumers will lose confidence in products containing chemicals being "phased-out".

A major problem with this idea is the definition of "credible scientific evidence". What does this mean? For example, would the evidence rejected by the EPA's Scientific Advisory Panel regarding Alar be considered "credible"? I look forward to exploring this question.

Also, I have to question the fundamental notion of a "phase-out" of pesticide registrations. In addition to my concern that it would encourage EPA to circumvent the FIFRA cancellation process, I believe that some sort of gray area for pesticide registration status is irresponsible.

A chemical is either safe for use or it isn't. To further confuse the issue by instituting a "phase-out" does a disservice to producers, possessors and consumers. With "phase-out" the EPA may just want a tool it can use to manage public opinion disasters, but it will come at the expense of sound public policy.

The proposal would extend current Farm Bill pesticide recordkeeping requirements on restricted use chemicals to all chemicals, for farmers only. This prompts me to ask: if non-dietary exposures are going to be considered in tolerance setting, why not extend recordkeeping to all uses of chemicals?

Currently registered pesticides would be lost if EPA failed to meet its own pesticide residue review deadlines like registration sunset and 7 year tolerance review. In effect, the private sector would be punished for EPA's failure to do its job.

President Clinton calls for the development of IPM programs and implementation strategies for 75% of acreage within 7 years. Just like conservation provisions in the Farm Bill, I fear that a goal today will easily become a requirement tomorrow.

Under this plan the EPA will attempt to assess and identify non-dietary exposure in the home, water, lawn, work place, and elsewhere, including these in tolerances. Agriculture's ability to use a chemical which can be controlled and measured would ultimately be limited by other uses which cannot be controlled or measured on a national basis.

At the same time the Administration is requesting at least \$19 million in current fees and unknown amounts of new fees, despite the fact there has been no detailed, satisfactory accounting of how previous fee funding has been expended by EPA.

The proposal fails to address the issue of national uniformity. I believe a national tolerance uniformity provision is necessary in pesticide regulation to avoid consumer confusion and unreasonable burdens on interstate commerce caused by a patchwork of state and local regulation.

Finally, President Clinton calls for a "carefully crafted" provision for citizen suits under FIFRA and possibly under FFDCA. Individual private citizens would be given standing to file suits regarding enforcement of pesticide regulations on farms.

I would find it difficult to seriously consider accepting legislation with so many major faults. However, this Committee is not without alternatives.

Some observers are suggesting the Administration's proposal is a compromise between HR 1627, the Food Quality Protection Act and HR 872, the Pesticide Food Safety Act of 1993, commonly known as the Kennedy/Waxman bill.

The Administration's recommendation is clearly not a blend of the HR 1627 and Kennedy/Waxman. The Administration's proposal is a third approach to our pesticide policy, which at this time bears critical examination.

I look forward to hearing the witnesses' testimony on President Clinton's pesticide proposal. However, I would like to point out that legislation already exists that represents a balanced solution for federal pesticide policy.

HR 1627 currently enjoys 119 cosponsors, from the House Committee on Agriculture, from the House Committee on Energy and Commerce and among the membership of the House. At the same time, the Waxman bill has one cosponsor and Senator Kennedy has none on his legislation. In addition, HR 1627 enjoys widespread support from the agriculture and food processing community, with endorsements from over 230 organizations.

HR 1627 would provide the EPA the regulatory authority needed to more quickly eliminate the use of pesticides under the cancellation process, and remove time consuming paperwork constraints that have in the past slowed EPA efforts to prohibit the use of pesticides in emergency situations.

The Delaney Clause, while well-intentioned 34 years ago, has become an anachronism that must be replaced by a sound standard of negligible risk. If the Administration hopes to play a significant role in developing a resolution, their proposal is going to have to be much more specific in the area.

In any event, this will be a long and difficult process. In the meantime, I would like remind the Administration witnesses that this Committee has demonstrated time and again its confidence in the Executive by incorporating considerable discretionary authority into our legislation.

I think I can speak for my colleagues in saying that we expect these authorities to be used to resolve, not create, crisis for our nation's farmers, ranchers and consumers.

Again, Mr. Chairman, thank you for calling this hearing. I look forward to hearing the testimony of our witnesses and listening to their answers from this panel.

Mr. STENHOLM. Ms. Lambert.

**OPENING STATEMENT OF HON. BLANCHE M. LAMBERT, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ARKANSAS**

MS. LAMBERT. Thank you, Mr. Chairman, and thank you for addressing such a difficult issue here today.

Revision of the Nation's pesticide laws has been a contentious issue before the Congress for several years with little progress being made, but due to the *Les versus Reilly* decision, we now have added incentives to work through the aspects of policy that have been roadblocks for so long.

With that in mind, I congratulate the administration for coming forward with such a comprehensive proposal, and I am particularly pleased that the health of our children is the main component of the package. That is not to say that the proposals are perfect, for we certainly know that no legislative package ever is, but finally we are all at the table and committed to moving forward and I think that is a tremendous beginning.

Throughout this debate there is one element that has been overshadowed by the potential negative effects of pesticide use, and that is the benefit that we all accrue from production agriculture. I, for one, think that the National Academy of Sciences said it best when they stated in "Pesticides in the Diets of Infants and Children" that "pesticides are used widely in agriculture in the United States. Their application has improved crop yields and has increased the quantity of fresh fruits and vegetables in the diet, thereby contributing to improvements in public health."

Clearly, there are areas that need improvement and reform, but people on all sides of this issue should remember that the health benefits that we all receive from production agriculture are immense in this Nation. I certainly look forward to today's testimony.

Thank you, Mr. Chairman.

MR. STENHOLM. Regarding all members of this subcommittee, I hope that you will be prepared over the next few weeks now to do as Mr. Smith encouraged, and that is to look at the best of all of the proposals. I think that is going to be one of the keys.

We are going to work awfully hard over the next several weeks regarding doing that which Mr. Gunderson, in somewhat gloomy yet hopeful analysis of our past record in this endeavor, said.

Mr. Gunderson, one observation that is fairly obvious to me. We have a new chairman of this subcommittee. We have a new administration. And with your guidance—and a new ranking minority member—this year we are going to get it done.

MR. GUNDERSON. Mr. Chairman, there is no question that once we got Pat Roberts out of the way, I knew we could make progress.

MR. STENHOLM. I call our witnesses to the table. Ms. Browner, Mr. Rominger, Dr. Kessler, we welcome you to the subcommittee. We welcome each of you this morning. We look forward to hearing your testimony. You may proceed in the chosen order that you have decided to proceed with.

**STATEMENT OF CAROL M. BROWNER, ADMINISTRATOR, U.S.  
ENVIRONMENTAL PROTECTION AGENCY**

Ms. BROWNER. Good morning, Mr. Chairman, Mr. Smith, and other members of the subcommittee. We are pleased to appear before you today to present the administration's views on pesticide use and protecting the food supply.

I want to thank Chairman Stenholm, Chairman de la Garza, and Mr. Roberts for their leadership on these very difficult issues.

I want to also acknowledge that food safety is not an easy issue. It is an emotional subject. The proposals that we present today represent the efforts of a wide variety of people, including many fine people from the agricultural community, to harness our expertise, our urgent concern, our best science, and our most passionate caring for the benefit of our children and all Americans.

The Environmental Protection Agency, the Department of Agriculture, and the Food and Drug Administration have worked very closely in developing this proposal, in a way, that quite frankly, I don't believe these three agencies have ever before worked together on this issue. We have also worked with farmers, environmentalists, consumer groups, and State agencies.

Today, we are proud to present a program that we believe will reduce the many health risks posed by pesticides and improve the safety of our food supply, especially for children. We believe today's proposal is a giant step forward, an opportunity to break the log-jam of competing and vested interests to ensure a rigorous standard for food safety that all Americans can rely on.

The need for change is urgent, as so many of you recognized in your opening statements. Nationwide, we use more than 1 billion pounds of pesticides each year. Of the 600 pesticides now in use, two-thirds have not been subject to a health-based standard review. We cannot and we will not tolerate the status quo.

The solution is to make substantial changes in two laws. First, to assure a greater degree of safety in the food we eat, we must reform the Federal Food, Drug, and Cosmetic Act. But the risks of pesticide use extend far beyond the dinner table. We need to protect the farmers, farmworkers, and homeowners who handle pesticides, and we need to decrease the threat to the plants and animals with which we share our world. For this reason, we must also reform FIFRA.

Let me describe the major provisions of our proposal.

First, we propose to take special steps to protect children. We have already committed to implementing the recommendations made by the National Academy of Sciences in June in a report entitled "Pesticides and the Diets of Infants and Children," which several of you made reference to.

Today, we propose that the law be changed to require EPA to make a specific finding of safety for every pesticide used on every food, particularly those eaten in large quantities by infants and children. This will require us to account specifically for the unique diets and susceptibilities of children.

The National Academy of Sciences also suggested we look at exposure to pesticides in lawn care chemicals, drinking water, insecticides used in the home. We will follow this recommendation as

well. I feel strongly that these steps are absolutely necessary to ensure an appropriate level of protection for our children.

Second, we propose to establish a uniform health-based standard that applies to all pesticides, all foods, all risks to human health. We propose to reduce pesticide residue levels in food to ensure a reasonable certainty of no harm to consumers, again, following a recommendation of the National Academy of Sciences.

Third, we call for strict new deadlines to ensure that all pesticides comply with the new standards within 7 years.

The fourth part of the administration's proposal is to make good on our June 25 pledge to encourage a dramatic reduction in pesticide use. Yesterday, EPA and the Department of Agriculture announced that within 1 year we will develop specific goals for reducing pesticide use by the end of the decade. We will include farmers, environmentalists, and other interested parties in establishing these goals and developing implementation plans.

We are also proposing that by the year 2000, 75 percent of America's farmland will be using integrated pest management methods. We are confident that we can reduce pesticide use and pesticide risk without any decrease in the quality of our produce or the output from our farms.

Let me briefly mention three other provisions of our proposal. First, under current law pesticide registrations are essentially good in perpetuity. We propose that the law be changed so that pesticide registrations would be renewed every 15 years. This requirement will ensure that all pesticides conform to the latest scientific standards, and it will promote the development of safer alternatives.

Second, we would make the registration of these safer pesticides a top priority.

And third, we would prohibit the export of pesticides that have been banned in the United States because of health concerns.

Before closing, Mr. Chairman, I want to add a personal note. I come from Florida, where agriculture is a key industry. In carrying out my responsibilities in Florida as the head of that State's environmental agency, I worked very closely with the farming community. It was my experience that farmers wanted to use fewer pesticides. They were eager to use alternative methods of pest control that were safer for the community and the environment.

I want to also say that it is vitally important to me as the head of the Environmental Protection Agency and as the mother of a 5½-year-old that there be absolute confidence about the food on our dinner plates. I am proud to say that today's proposal offers a higher level of protection than any pesticide package ever presented by any administration.

It has been a real pleasure to work with my colleagues, Secretary Rominger, Commissioner Kessler, Secretary Espy, on this very important matter. Now we look forward to working with farmers, consumer advocates, and this subcommittee, as we move forward with legislation to deal with these very pressing problems.

Thank you very much for the opportunity to be here today.

[The prepared statement of Ms. Browner, Mr. Rominger, and Dr. Kessler, appears at the conclusion of the hearing.]

Mr. STENHOLM. Thank you, Ms. Browner.

Mr. Rominger.

**STATEMENT OF RICHARD E. ROMINGER, DEPUTY SECRETARY,  
U.S. DEPARTMENT OF AGRICULTURE**

Mr. ROMINGER. Thank you, Chairman Stenholm and members of the subcommittee, for the opportunity to discuss our proposals to improve the regulation of pesticides.

Early in the summer, Secretary Espy asked that I represent the Department of Agriculture in the interagency discussions, and therefore I am here to present his views. He certainly looks forward to working with each of you in achieving the goals of the administration, which we are discussing here today.

We have presented written testimony of 60 some pages in detail. I would like to briefly mention some of the highlights here this morning.

We believe that the interagency process has produced a proposal, the net benefits of which are greater than the sum of its parts as viewed separately. I believe that this is an important point to keep in mind as you analyze for yourselves the merits of the proposals we are discussing.

We are presenting a proposal which will provide the starting point for further discussion. However, this proposal does meet the most important objectives announced on June 25 when we began this process. Specifically, it will increase the safety of the food supply, including the special needs of infants and children.

In addition, these initiatives represent further help in moving production agriculture into a future with a far greater emphasis on sustainable and environmentally sound practices.

Primarily our food safety goals are met by the tolerance review proposals under the Food, Drug, and Cosmetic Act. We also intend that actions to remove unacceptable risk posed by pesticide use will take place under a more timely and appropriate process through improvements in the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA.

As I stated a moment ago, we are committed to the continuing development of alternative pest management tools that will enable agricultural producers to reduce the risk and the use of pesticides through incentives to further encourage the development and registration of new materials.

The Department of Agriculture is committed to reaching a consensus with EPA and FDA on the best public policy course and to resolving the complicated and emotional debate over pesticides and food safety. With the leadership of the White House's Domestic Policy Council, we devised solutions that we hope will serve as an example of how the disparate interests, constituencies, and philosophies in this debate can be reconciled.

We offer our approach in developing these proposals as a model for how Federal agencies can coordinate their efforts in an efficient manner to serve the public interest.

For our part at the Department of Agriculture, we have come a long way in our effort to address the impacts of agricultural practices and in our commitment to ensure that farming in this country is environmentally as well as economically sound.

One concrete example which demonstrates our interest in becoming more proactive in these areas was announced recently as part of our proposed reorganization. Specifically, the Secretary has rec-

ognized the need and will fill a long-standing gap by dedicating a specific office within our Environment and Natural Resources Agency to coordinate policy internally and with other agencies on pesticide and environmental policy. We look at this step as a means to follow up on the unprecedented cooperation that has been established among EPA, USDA, and FDA.

In addition to our participation in developing the administration's proposals, we have taken on important and specific responsibilities to ensure the protection of children and reduce the risks from pesticides. For example, we have committed to increasing the quantity and quality of information to be used in assessing exposure, particularly for children, to pesticide residues, and to developing new pest management alternatives which address the needs of growers and the environment.

We intend to significantly strengthen our food consumption surveys so we can accurately assess the diets of infants and children. This effort will build on the program currently underway by increasing the size of the survey and making the data base truly useful to the decisionmaking process. We need specific science to make sound decisions.

We also intend to improve our ability to understand and analyze the use of pesticides in the United States. It is critical that we have high-quality information on pesticide use in order to make percent of crop treated determinations and for measuring progress in pesticide reduction efforts.

Coupled with an increase in recordkeeping requirements, we will increase the number of States and crops covered in our use surveys in order to ensure that we have complete and accurate data.

Farmers eagerly embrace new science, and the Department of Agriculture has a long and successful history in providing farmers with the latest production tools through its research and extension programs. We propose to intensify those efforts, to set environmental goals for our research programs and to direct research specifically into alternatives to pesticides which pose unacceptable risks to human health or the environment.

A number of agencies at USDA have developed and provided for the use of biological pest control methods which are effective and environmentally safe. These materials include pheromones developed through the Agricultural Research Service and the Cooperative State Research Service to replace insecticides as well as non-agricultural materials developed by the Animal and Plant Health Inspection Service and the Forest Service.

We are proposing specific statutory direction in section 28 of FIFRA to establish a structure for USDA to work with EPA in setting research priorities for the development of substitutes for pesticides which have been determined to pose problems and for which there are few or no other pest management options. This process will ensure that we anticipate and deal with health or environmental problems to reduce risk and help ensure that producers continue to have the pest and disease management tools necessary to raise their crops and to have enough profit to plant again next year.

We will also move to establish a program to assist in the collection of data to help support minor crop registrations. While it is

difficult to talk about funding new programs in the current budget environment, the program would ideally provide matching funds with the grower community to support needed studies.

This program would be in addition to our proposal for full funding of the IR-4 program, and that program helps support the development of health and safety data needed for the continued registration of minor-use pesticides. A goal will also be set for the implementation of biologically based integrated pest management programs on 75 percent of the Nation's acreage by the end of the century. These programs will be based on biological and cultural controls, the consideration of environmental factors and pest management decisions, and the use of chemicals as a last resort.

With the cooperation of EPA, we also intend to target areas of high-pesticide use for demonstration projects that have appropriate pesticide use reduction goals. We already have experience with these sorts of projects in ground water protection efforts where we have identified highly vulnerable areas in order to improve water quality.

For example, a USDA national study released late last year developed a soils rating system which was then used to identify areas where the leaching of pesticides into ground water is likely to be a problem. With this information, a farmer can take action to reduce the potential for ground water contamination, for example, by selecting a pesticide with a lower tendency to leach.

When surface water contamination is a potential problem, tail water return systems or holding ponds could be a solution. The achievement of the ambitious goals I have just outlined demonstrate that the Department of Agriculture is ready to take a new leadership role in moving American agriculture into an era of profitable production with a reduced reliance on chemical pesticide use.

Obviously, American farmers have an enormous stake in the debate over food safety and pesticide legislation. Our proposals meet their needs in several ways. We set a single science-based food safety standard based on realistic data to further protect their families and families across the country.

We provide for benefits consideration in setting of tolerances which takes into account significant disruption of domestic production and which offer the opportunity for reducing risks and making transitions. We provide straightforward and timely processes by which unacceptable risks from pesticides can be eliminated.

Through both of these measures, we strengthen public confidence in the safety of the food supply which is critical to farmers and consumers. At the same time, we will intensify our efforts to develop new pest management tools and to get them into the hands of producers where they can have practical value on the farm.

Farmers, growers and ranchers in the United States have long appreciated the need to protect the environment. This is a statement which is often made, but in my view one that is rarely fully understood or appreciated.

As the people who live on the land and depend on the land for their very livelihoods, agricultural producers have primary responsibility in their daily decisions for the safety of the food supply and the protection of the environment in which they live and work. As a lifelong farmer and one who has been active in farm organiza-

tions for many years, I can assure you that agricultural producers do take seriously the use of agricultural chemicals.

Long gone are the days, if they ever existed, of the indiscriminate use of pesticides. Pesticides are expensive and when not used properly some of them can be extremely dangerous to anyone applying them, so it seems to me our job as policymakers is to help farmers make the transition which they are already making. In fact, I believe that we now find ourselves in a situation where a great number of farmers are ahead of the policymakers in their desire to find and use alternatives to expensive chemicals and to use methods which will lead to a more sustainable agriculture.

The administration, including the Department of Agriculture, wishes to provide the leadership our farmers need and want, while also helping them through what will undoubtedly be a period of transition and uncertainty.

Mr. Chairman, on a number of occasions you have mentioned that public confidence in the food supply is the key to continued success of America's farmers and ranchers. At the same time, it is critical to this administration that in gaining public confidence, we also ensure that agriculture remains strong.

At the Department of Agriculture, we are absolutely committed to doing everything possible to provide producers with the means to meet the Nation's food and fiber needs.

Again, I want to thank you for allowing us this opportunity to present this testimony and we will be happy to answer questions. Thank you.

Mr. STENHOLM. Thank you, Mr. Rominger.  
Dr. Kessler.

#### **STATEMENT OF DAVID A. KESSLER, M.D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Dr. KESSLER. Thank you, Mr. Chairman, Mr. Smith, members of the subcommittee, for this opportunity to share the views of the Food and Drug Administration on this very important subject of food safety and pesticide regulation. We are here today to deliver on the commitment of this administration to maintain and improve the safety of the food supply and to reform pesticide regulation.

When it comes to food safety, easy assumptions about the status quo must be replaced by the greater safety of a strong health-based standard. Under today's convoluted system of pesticide regulation, there is one standard for grapes and another one for raisins, one standard for fresh tomatoes, another one for tomato paste. The reforms we present today would establish for the first time a strictly health-based approach to the regulation of pesticide residues in foods. This is a historic shift. We will move from the status quo with its conflicting standards and unduly burdensome procedures to a strict health-based safety standard.

To the American consumer, the shift means nothing less than real tangible food safety reform. I firmly believe that we will enhance the safety of food by adopting for pesticides the same kind of health-based safety standard we have applied for many years to most chemicals used to produce our food.

Using the best available science, pesticide residue tolerances would have to be set at levels that ensure a reasonable certainty of no harm to consumers. For potential carcinogens, the estimated risks would have to be negligible. This new safety standard would replace the multiple and conflicting standards of current law, including on the one hand the standard that historically has governed most of EPA's pesticide decisions which allows the weighing of risks and benefits, and on the other hand, the Delaney clause, which applies only in the minority of cases, when the pesticide residue concentrates in processed food above the level allowed on raw commodities.

The new bottom line is that foods will be safer, because older pesticides, which may pose a greater than negligible risk, will have to be reevaluated under a strong health-based standard.

Our approach provides fixed timeframes for the removal of pesticides that fail to meet the new standard. Manufacturers of pesticides that pose a greater than negligible risk will be required to lower that risk to negligible levels. If they cannot, then the pesticide must come off the market.

But to ease the transition to this new health-based standard, a nonrenewable time limit extension of tolerance could be granted. But only in the extraordinary circumstances where the pesticide is needed to protect the public health or to avoid a significant disruption of the food supply.

As significant as our shift to a health-based standard is our focus on infants and children. Our proposal recognizes the safety of pesticides should be evaluated not only with reference to the average person, but when the tolerance is set the safety of the pesticide needs to be established for children as well. That means taking into account children's unique sensitivities and exposures.

The administration's plan will require that any tolerance protect children as well as adults. We will invest in more detailed and reliable consumption data, especially for foods kids eat in large quantities. We will refine our scientific methods for identifying and assessing the hazards pesticides may pose to the young. We will seriously consider all the recommendations of the National Academy of Sciences report on "Pesticides in the Diets of Infants and Children."

When it comes to America's children, we cannot afford to cut corners. These food safety reforms, the shift in regulating pesticides, the uniform health-based standard, all of these elements are about one thing, they are about protecting the public. Our proposals will improve public health by applying strict health-based standards to pesticides in foods, paying special attention to infants and children, and improving the ability of the Federal Government to act.

In sum, we are talking about transforming a system of regulation. We look forward to working with you and your colleagues on the Energy and Commerce Committee and in the House and Senate in the weeks and months to come. It has been an extraordinary opportunity to work closely with such colleagues as Secretary Espy and Deputy Secretary Rominger, Administrator Browner and White House Domestic Policy Advisor Galston.

Thank you very much, Mr. Chairman.

Mr. STENHOLM. I thank each of you.

As soon as Mr. Roberts gets back, I will recognize the ranking minority member of the full Agriculture Committee for his opening round of 5 minutes of questions.

Mr. Roberts.

Mr. ROBERTS. Richard, how are things in California? Have you got Jerry Brown talked into supporting NAFTA yet?

Mr. ROMINGER. I have not talked to Jerry Brown about NAFTA.

Mr. ROBERTS. All right. I want to mention the fact that I am concerned about the lack of the printed word in regards to the concept of benefits in the administration's package. I am not trying to perjure that, it is just that I am concerned about it. And I think there may be a fundamental misunderstanding in regards to benefits.

I got a question yesterday that we are going to respond to by Congressman Bilirakis of Florida, to the criticism that benefits are simply an increase in the public's risk of disease so that a few producers can make money. And I think that this is a misunderstanding because the Government did utilize the cost to farmers of losing a pesticide as a cost to society at large.

I want to point out that under H.R. 1627, we are trying to take a new look at benefits to ensure that the public understands why they are being considered. And under H.R. 1627, it defines a benefit as a health, nutritional, and consumer benefit, including the impact of the loss of a pesticide on the availability of an adequate, wholesome, and economical food supply. No impact on pesticide manufacturers or distributors may be considered.

Now, I am a little concerned—well, let me go on and say that a new study by Texas A&M, this was a question asked by Congressman Bliley yesterday, shows that without pesticides the availability of a domestically produced fruit and vegetable crop would drop by 70 percent. And this gets into the risk-benefit standard discussion.

We have had a drastic reduction of pesticide uses that have resulted from the lack of any real action on the reregistration effort. I am not trying to point the finger at EPA or the Agriculture Committee or Energy and Commerce Committee or whatever on the slowness of that effort, but there have been 14,000 uses that have been discontinued because the requirements and that treadmill are so slow, that it is so expensive, that it is impractical to maintain the registration.

So that means our producers must depend on fewer and fewer chemicals to maintain the production for consumers. Consequently you could make the argument that the consumer in this country could be denied an adequate supply of fruits and vegetables, which is exactly what the National Academy of Sciences is recommending to prevent cancer.

Now, having made that statement, my question pretty much is to Secretary Rominger. Your position on benefits calls for an end to benefit considerations for a chemical by a date certain. And I was a little concerned about that. I don't know if on 1 day of the calendar you have a benefit, and then by date certain you don't, I don't know how turning the page on the calendar can nullify that gain for the consumer. And if there is not a substitute, what do we do about that?

And another concern is the feeling, and I don't know if this policy is stated, that somehow we can import that particular crop. That might be in keeping with NAFTA, but I am not too sure some of the people on this subcommittee would agree with that.

Could you address my concern in this regard? Where are we on benefits, and what about that time problem?

Mr. ROMINGER. Yes, I will try to answer your questions, Mr. Roberts. We do have a proposal in here that will take into account benefits and I will refer to that in a second, but I certainly do want to emphasize that we intend to keep a good supply of fresh fruits and vegetables, among other products, for the people of the United States, and that most of those will be domestically produced.

But on page 12 of our detailed statement, we say that we propose to give EPA the authority to maintain tolerances for a nonrenewable period of no more than 5 years for a chemical that does not satisfy the standard if it is justified to maintain direct health benefits to consumers or to avoid significant disruption in the food supply. And we are referring to the domestically produced food supply.

And we go on to say that tolerances still not meeting the safety standard at the end of that extension period could only be renewed if Congress enacted a statutory exemption. So there is that escape clause at the end of the 5-year period if we still haven't been able to reduce the risk below the negligible level. But we would certainly be working during those 5 years to reduce the risk by perhaps modifying how the chemical is applied, maybe it is a matter of worker protection, additional worker protection. We think there are a number of ways that we would be working to reduce the risk posed by that particular chemical.

Mr. ROBERTS. I beg the indulgence of my colleagues. I see the red light is on, but let me give you an example.

Under the Clean Air Act, methylbromide, which is a very important soil fumigant, and we also certainly use it in regards to grain as an export safeguard, is going to be phased out in the year 2000 no matter what the consequences are. Now, some substitutes might be found, but there is no substitute right now, and that is what I am talking about, because it could clearly endanger our exports, and again that is the key example.

But what do we mean by significant disruption of domestic production? Is that a 10 percent loss, a 50 percent loss?

Yesterday Administrator Browner mentioned that term. Can we tie that down a little bit? Obviously a 10 percent loss to a wheat farmer or a corn farmer is significant. I don't know what a severe or significant loss is. That is the kind of thing that I think we need to work on.

Mr. ROMINGER. We have not set a percentage figure on that. We would welcome this subcommittee or others in Congress to do so if they choose.

Mr. ROBERTS. We would probably be fixing a new Delaney figure into a significant loss. I am a little worried about that. Five percent might be significant to a producer.

I look forward to working with you on the whole issue of benefits, and I thank you for your time.

Mr. STENHOLM. In your testimony, you addressed pesticide use regulation. Don't you really mean pesticide risk reduction? It could be arguably stated that one can actually reduce the use of a product, yet increase the overall risk to health.

Mr. ROMINGER. We are talking about risk reduction, yes. Certainly that is the goal of this, is to reduce the risk posed by the use of pesticides. And in some cases that will result in the reduction in the use of a particular pesticide.

Mr. STENHOLM. I should not draw the conclusion that you are emphasizing use, it is really risk that we are talking about?

Mr. ROMINGER. They both go together, I think, but we are focusing on risk.

Mr. STENHOLM. Regarding enforcement in your recommendations, why is a right or private right of action needed?

Ms. BROWNER. Mr. Chairman, the proposal does include what we would call a check and balance in the system. If there is the belief on the part of a private citizen that the Agency, in this case the Environmental Protection Agency, is not doing its job, then they would be allowed to move forward only after consultation with the agency and the agency's continuing reluctance to do the job, with a lawsuit.

These are provisions that we have in a number of our laws that we manage at the Environmental Protection Agency. I will tell you that we are embarrassed when people have to use them. It is an indication that we have not done the job that we are supposed to be doing. But quite frankly, they are rarely used, because when a citizen brings to our attention that we may not be acting in accordance with the law, we take that seriously. If we believe we are, we inform the citizen, and we inform the court.

Mr. STENHOLM. Are you recommending that this apply only to EPA or does this include States and individuals and other agencies as part of—

Ms. BROWNER. We are recommending that the citizen suits provision apply to all FIFRA violations.

Mr. ROMINGER. We are also crafting this so that it does not result in the harassment of farmers.

Mr. STENHOLM. That was my next question. What are EPA's intentions regarding inspection of farms and application records? Search warrants, for example, and what about FFDCA enforcement?

Ms. Browner.

Ms. BROWNER. Mr. Chairman, I am leaving the FFDCA enforcement to Dr. Kessler. But first of all, I want to be very clear with the members of this subcommittee, it is not our intention in any way to harass farmers. We want to work together with the farming community and with USDA to deal with these very complex issues.

I think we all agree that recordkeeping will provide us with very important information in terms of tolerances so that we can provide the public with the assurances that they need about the safety of our food so that farmers can continue to deliver their food to market and see it sold. A large component of the package deals with the public and making sure that they understand that we have a safe food supply in this country, giving them those assur-

ances so all of us who do the work in delivering food to the public can continue to do that work.

Mr. STENHOLM. Dr. Kessler.

Dr. KESSLER. Mr. Chairman, the remedies under the Food, Drug, and Cosmetic Act, there are only a few, and they are pretty strong. I mean they are seizure, injunction, criminal prosecution. And they don't always fit.

The recommendation for civil money penalties certainly may be much more appropriate, a fine, than going into court and filing for an injunction or certainly criminal prosecution. So I think there the issue is what the appropriate enforcement response is.

There are cases where we have had difficulty because of the limited nature of our tools, for example, if we find illegal violative residues on a product, we have to go file for a seizure action. Sometimes we turn around and find that the material has left. I mean, we have not been able to secure that material pending our going into court.

That was the reason for the embargo. Most people think that I can order a recall of food. I can't, and in fact we have had cases where we have had illegal violative residues of pesticides on certain products and some of them got distributed and we have to literally go chase those products. We can't order a recall, which I think would be much more efficient, assuming that there are appropriate protections on those enforcement mechanisms.

Mr. ROMINGER. Mr. Chairman, I would like to add something on the recordkeeping portion, if I could. We are talking about asking farmers to keep records on their pesticide use so that we can have that information available through our surveys. We are not asking for reporting, just recordkeeping.

We would, through our surveys, then be able to better determine what percentage of the crop is being treated, at what rates it is being treated, and would then be able to set more realistic tolerances on those pesticides. And we retain the confidentiality and the limitations on access that are in the 1990 farm bill. There would be no change in that part of it.

Mr. STENHOLM. Thank you.

Mr. Smith.

Mr. SMITH of Oregon. Thank you, Mr. Chairman.

Administrator Browner, on this issue of citizen suits, I come from the West and I have experienced, as most in the West have, the intervention of the administration's policies with respect to timber harvest. And we have had a round in the last 5 years of lawsuits which has, from both sides, which has eliminated the opportunity to harvest timber basically, left the decision to the courts. And many of those lawsuits have been frivolous in nature, meant to delay.

My question to you then, have you thought carefully about the idea that you are going to allow every activist organization in the country, some of which want to eliminate all pesticides, that is their purpose, yours is to phase them out, I understand, but any action you may take will be appealed by one side or the other, you will be hamstrung, you will be in court forever, and your policy will never be carried out. Have you thought about that?

Ms. BROWNER. We have, Mr. Smith, thought long and hard about this. In fact, we engaged in many hours of discussion about this recommendation. It is not in any way our intention to allow for or encourage frivolous lawsuits.

Mr. SMITH of Oregon. I understand.

Ms. BROWNER. We at the Environmental Protection Agency are literally sued every day, and it does have an effect on our ability to do our job. But we do believe that giving citizens the right to make sure that EPA is doing what the Congress has directed us to do, is an appropriate check and balance to the system.

And again, the citizen, before they proceeded to court, would be required to contact the Environmental Protection Agency to set forth their criticism of how we are doing or failing to do our job, and that we would have to respond to that and work with the group to see if we could resolve the problem.

Mr. SMITH of Oregon. We found that that is where the 29 cent stamp, or maybe an increase in cost of stamps from those who are the activists in this country about anything you do.

But let me ask you, then, in your idea of this citizen lawsuit, may farmers be sued?

Ms. BROWNER. After a consultation with the agency, if there is a specific FIFRA violation, farmers could be sued.

Mr. SMITH of Oregon. Is that changed from today's situation?

Ms. BROWNER. They can be sued now by the agency.

Mr. SMITH of Oregon. But not by citizens groups, nor not by activists, nor not by those who want to bring this thing to a halt tomorrow morning, which there are many, as you know, we all know, who are waiting.

Ms. BROWNER. Mr. Smith, I think that we in the administration are more than happy to work with the subcommittee in terms of the specific details to make sure again that we don't have frivolous lawsuits, that we don't put farmers in a position of having to defend frivolous lawsuits. The goal here is to make sure the agency is doing its job and meeting the public's concerns.

Mr. SMITH of Oregon. Thank you.

In relation to that, on this question of disappearing chemicals, I understand from your proposal that pesticides would be lost if EPA failed to meet its pesticide residue review deadlines, for instance, registration sunset and 7-year tolerance review.

In this respect, with your advocacy of allowing citizens to sue and activist organizations to sue, doesn't that by EPA's own admission, if you decided, eliminate the opportunity for use of chemicals? If you don't act, you don't have any chemical available.

Ms. BROWNER. Mr. Smith, first of all, I think we all recognize that the reregistration program, and Mr. Roberts made reference to it, has not moved as expeditiously as we would like to see. We believe that we do not have all of the tools to make sure that we move in a timely manner, to give the public the answers that they want to ensure the confidence in the food supply.

We are asking in this package for a number of tools that will allow us to move quickly to deal with registration issues. If the agency fails to act within the timeframes, then an extension could be granted. But the burden in terms of providing the information

to the agency would be shifted to the producers, and so we do believe in most instances we will be able to act in a timely manner.

The current situation in terms of the data collection is very difficult for the agency and it does contribute to the delays.

Mr. SMITH of Oregon. I understand. But see, my point is simply, certainly not you, but a devious EPA Administrator who wanted to eliminate all chemicals could merely sit on your hands and therefore there would be never again—the chemical would run out of time, and therefore—

Ms. BROWNER. Mr. Smith, there is a provision in our proposal which states that if the data has been submitted, the data package is submitted from the manufacturer or the registrant, and the agency has not acted, an extension is granted to the manufacturer. So the burden is now on the agency to act.

So we did deal with that, we believe, and we are happy to work on specific details if you feel like we haven't dealt with that contingency.

Mr. SMITH of Oregon. But if I didn't want to extend the time, I wouldn't have to, right?

Ms. BROWNER. No. If the data has been submitted from the registrant and EPA has not acted, there is an extension.

Mr. SMITH of Oregon. Automatic?

Ms. BROWNER. There is an automatic extension.

Mr. SMITH of Oregon. So I understand it is a 1-year extension. After that it is all over?

Ms. BROWNER. Well, we are more than happy to work to make sure that the concerns you raise are addressed. It is not our intention to sit on our hands. It is our intention to get the information to make the decision.

Mr. SMITH of Oregon. And it is not my intention to accuse anybody of anything. It is my intention to create fairness in this operation so a devious—there aren't any—but a devious person in the EPA couldn't stop by merely not acting, all chemical renewals.

Ms. BROWNER. We would be more than happy to work with you.

Mr. STENHOLM. We are always happy to have the chairman of the full committee, Mr. de la Garza, with us. We recognize you at this time.

The CHAIRMAN. Thank you very much, Chairman Stenholm, and I thank the three witnesses for appearing and bringing the recommendations from the administration. We look forward to working with you. And if I have a question, it is that—to all three of you, whoever is the senior might answer—may we expect your cooperation in the dialog that is to follow, speaking for the administration with one voice?

Mr. ROMINGER. Yes, you certainly may expect our full cooperation.

The CHAIRMAN. Because that has been a problem in the past, turf or professional differences or whatever.

But your message to us on behalf of the administration is that all the three agencies will cooperate and speak with one voice?

Mr. ROMINGER. We will continue to coordinate our work and we will continue to speak with one voice.

The CHAIRMAN. And we may have the benefit of that as we proceed?

Mr. ROMINGER. Yes, you certainly will.

The CHAIRMAN. I have been dealing with FIFRA since I came to the Congress and it is a very emotional issue for some. It is a matter of life and death in the health for many. Pesticides are a tool used in agriculture, to have better quality, to have more production. The regulatory balance has to be arrived in a factual, scientific way, and we hope that your cooperation in that respect will supersede any outside emotional media hype or one-issue groups.

One-issue groups are always slanted to their one issue and we don't have the benefit of discerning between one side and the other. You will be our expert. We have no major expertise from professionals in our shop and we will expect to get that from all three agencies. I would hope that that is a commitment that we can make here today.

Mr. ROMINGER. Mr. Chairman, we certainly do make that commitment that all of us will continue to work with you and the other members of the committees in putting forward what we think is a good, balanced, comprehensive food safety program.

The CHAIRMAN. Dr. Kessler, you have a great professional combination, doctor/lawyer, so you can see it from both sides, or all sides.

Let me just ask you as to the current tolerances methodology, is it FDA policy to consider some form of gain before you consider setting the tolerance or taking the risk?

Dr. KESSLER. We work with the Environmental Protection Agency and it is EPA that sets the tolerances. Our job is to enforce them. But we set tolerances for food contaminants other than pesticides in a number of instances.

And let me tell you what our experience is. It is one of the central issues today. We talk about what is the standard and how to include benefits. And I think if you understand what we go through in our scientific thinking, as you said, I think you will see that a logical way to put it together is the kind of package that we put forward for your consideration today.

We can assess scientifically what the risk is of a chemical. We have all gotten to the point when we are dealing with small residues, I mean the increase in analytical methodology of detecting small residues, certainly is the real problem with Delaney. And we have generally come to the use of quantitative risk assessment. And the use of this 1 in 1-million lifetime cancer risk, I mean, is as close to zero, is for all practical purposes, zero additional cancer deaths from the use of the chemical.

But let's say a chemical poses 35 additional deaths or 200, according to quantitative risk assessment. Everyone says risk-benefit sounds great. You add up all the risks and then you add up all the benefits and you weigh them. Well, Mr. Chairman, it is not that easy.

The problem is, if the quantitative risk assessment predicts there is another 225 additional cancer deaths that are possible, I mean, from a chemical, how do you weigh that against benefits that are not equally health related? That is why I think that the standard that we are proposing is a health-based standard. It does recognize, and there may be exceptional circumstances, that there may be cir-

cumstances in which there would be a significant disruption, and that is why we go to the transitional period.

The CHAIRMAN. Do we have a timeframe? Are you proposing a timeframe for action on this endeavor on behalf of the administration for Congress to act?

Mr. ROMINGER. Yes, the sooner the better as far as the administration is concerned. Yes, we would like to move expeditiously.

Ms. BROWNER. I might just add, Mr. Chairman, that as the agency that does have litigation pending against it with regard to these matters, we would certainly like to see the Congress move more quickly than not, so that we can deal with this in a comprehensive manner rather than responding to a case that focuses on a portion of the issue. But we will have to respect the court's order and the judge's order and move forward.

The CHAIRMAN. We have some legislation that we call, maybe it is a misnomer, minor-use legislation. Are you acquainted with that, in the reregistration of the so-called minor use?

Mr. ROMINGER. Yes.

The CHAIRMAN. Have you studied that? Does this fit into your proposal? Can it be piggybacked or incorporated into your proposals?

Mr. ROMINGER. We are certainly including minor-use registration concerns in our package, yes. We think that is an important part of the total proposal.

Ms. BROWNER. Mr. Chairman, as I understand, your proposal and our proposal—in fact, we have incorporated many of the concepts from your proposal. And it is an issue of great concern to me, again coming from Florida, where there are a number of minor-use crops grown.

The CHAIRMAN. There is no pride of authorship. Anyway it needs to be done, and anyway we can do it, and whatever vehicle. What we need to do is do it.

Dr. Kessler, let me mention personally that you might hear a lot of rumors, you might read a lot of media hype about differences between USDA and your agency in this respect and in other areas.

I wanted to assure you that nothing will be personal.

Dr. KESSLER. Thank you, Mr. Chairman.

The CHAIRMAN. We have great love, admiration, and respect for you. So any differences we might have, don't take them personally.

Dr. KESSLER. Thank you. But you need to know that the relationship between FDA and USDA, I mean, is very close, the relationship with Secretary Espy and Deputy Secretary Rominger.

The CHAIRMAN. And we hope that you consider the same with this committee.

My time has run out. But as I told your predecessor one time, you don't have any parent committee. You belong to us as to any other committee. The same as Mr. Rominger, the same as Ms. Browner. Because everything crisscrosses committee jurisdictions.

I might mention this in an aside, the *E. coli* outbreak in the West, the Secretary of Agriculture was sent to look at the issue, but it was FDA's jurisdiction.

Basically, someone didn't cook the hamburger patty for the length of time it needed to be cooked. That wasn't in the USDA realm or even in the EPA realm; it was in the FDA. But eventually

we learned that the tolerances for the heat were done by the States.

So, in fact, we may have sent the wrong person. But we are very proud of the way Secretary Espy handled that matter and the way USDA is addressing these issues.

But I do hope that you would consider this committee also your committee. And we will work with you. Like I say, we may have some differences, technical differences down the line as to jurisdiction of one thing or another, but none of that will be personal, I can assure you.

To the three of you, thank you very much. We look forward to continuing this dialog and hopefully, as you work with us and we with you, to resolve this issue. We have the best fed people in the world, in the history of the world, with the healthiest and cleanliest food in the world; but that doesn't mean we can't make it better. And that is what we are aiming for.

Thank you very much.

Thank you, Mr. Chairman.

Mr. STENHOLM. Thank you, Mr. Chairman.

Mr. Gunderson.

Mr. GUNDERSON. Thank you very much. Mr. Chairman, I want to try to ask a series of questions here in a short 5-minute time allotment.

First of all, is it my understanding there will not be a legislative document, that rather you hope to negotiate literally between the Waxman and Lehman bills conceptually? Or are we going to get a legislative document?

Mr. ROMINGER. We are prepared to work with the subcommittee in whichever way you choose. We have detailed written testimony here that covers—that is close to legislative language.

Mr. GUNDERSON. I don't think this is close to legislative language, Mr. Rominger.

Mr. ROMINGER. What I am saying is that it won't take long to put it in the form of legislative language if the subcommittee so desires.

Mr. GUNDERSON. OK. Do I understand correctly from your proposal that there will, in essence, be two tolerance levels for each pesticide?

In other words, we are going to have one negligible risk for, quote, unquote, the adult community and one for, quote, unquote, children?

Ms. BROWNER. Mr. Gunderson, there is one standard for all food for all risk. That is the reasonable certainty of no harm in the case of cancer. That is a negligible risk standard.

As it relates to children, the reasonable certainty of no harm, that is the standard.

The EPA, in setting a tolerance, needs to make a specific finding that children were taken into account; that their body weights, that their diets were taken into account.

The other exposures that children may be experiencing in terms of long-care chemicals, household insecticides, et cetera, were all taken into account. It would be a specific finding relating to children. But there would only be one tolerance. It is not as if you would go to the grocery store and there would be the fruit that was

OK for children and then the fruit for adults. That is not what we are suggesting.

Mr. GUNDERSON. So, in essence, the tolerance level for children will become the uniform tolerance level for approval of a registrant?

Ms. BROWNER. We are committed—as the National Academy of Sciences suggested to us—to take into specific account children in setting tolerances.

Mr. GUNDERSON. I am not being combative. I am trying to understand here.

So, in essence, we are going to have a new standard that is going to meet the National Academy of Sciences' determinants of what that standard of negligible risk ought to be for children, and that will be the uniform standard for everybody?

Ms. BROWNER. We believe, in many instances, the tolerances that we set today are protective of children. We believe that, in fact, that is what is occurring in almost every single instance.

But what we are committing to do is make a specific finding that, in fact, that is the case. There may be some situations where the tolerances need to be adjusted based on children, their other exposures, their diets, which are different from adults. And that would then be the tolerance that was set.

Mr. GUNDERSON. So there will be one tolerance, but there will be a requirement of a certain level of testing and data in the submission to meet the standard for children?

Ms. BROWNER. Precisely.

Mr. GUNDERSON. As of the 1988 FIFRA law and the reregistration of everything preceding 1984, what percent of those reregistrants are completed?

Ms. BROWNER. Actually—and I appreciate the question—of the 600 pesticides in use today, approximately 400 were placed in the reregistration program pursuant to the 1984 legislation.

The major use pesticides have been the initial focus of our energies. About 40 have now completed—

Mr. GUNDERSON. Forty of 400?

Ms. BROWNER. Now, again, we looked at the major use. So it is not appropriate to say that there are lots of pesticides being used on lots of foods that have not completed the reregistration process.

When we started our efforts, we said, what are the most commonly used pesticides? And we focused on those first. But we have to agree with you all, and that is why we are asking for changes in FIFRA relating to registration so that we can address the public's concern, so that we can make sure that we deal with these in a timely manner. We are not here to say that there haven't been problems in the reregistration program.

Mr. GUNDERSON. My concern is that, if you have this sunset provision when we have only completed 10 percent of the reregistration in the last 5 years, you are sending a real ominous signal to the industry that we are just not going to get this done.

Which gets into my next question. We already have, I think you say, a \$20 million shortfall in the necessary funds to do reregistration. You are talking about a one-time assessment in your proposal. But you are also talking about the ability to have an additional assessment to cover the reregistration process.

Have we got some numbers here? I mean what are we talking about in terms of total registration and reregistration costs so that the industry has some idea what these costs are going to be and we have some idea whether that is going to meet your financial needs to complete the process?

Ms. BROWNER. Mr. Gunderson, we do have that sort of information. We would be more than happy to provide it to the committee in writing.

If I could briefly go back to the 15-year sunset proposal that we made, that was not a randomly chosen year, 15 years. That is what we believe, based on an analysis of the workload we see, that it will take for us to do the job.

And we want to be honest with the subcommittee and with the public about what it is going to take for us to do the job.

Mr. Chairman, I see my time is out.

Mr. GUNDERSON. Your time is not out. Mine is. You can keep talking. You can extend it. I can't.

Ms. BROWNER. The chairman has graciously done that. Thank you.

The system—and maybe I could take a minute to explain the way it works in the reregistration program.

We solicit information from the registrant. We keep soliciting it. We try and put together a comprehensive package. We believe that there are better ways to make sure that the comprehensive package is delivered to us in a more timely manner so that we can act.

As I said to Mr. Smith, if it is our fault that we have not acted, not the registrant's fault because they have provided the information, then there is an extension available, an automatic extension to force the agency to act.

But I think we all agree that there have been legitimate questions raised about the reregistration process, about how the agency could move more quickly in terms of the economics, the cost associated with the reregistration process. And it is something we would like to work with the subcommittee to make sure that we have the tools to do the job, that we have the resources.

And we will provide you with that detailed breakdown in terms of cost associated with running a timely and effective reregistration program.

Mr. GUNDERSON. Just as a request, coming from Wisconsin, I would be delighted if you would also submit in writing the administration's position on the preemption issue, that our State and others can figure out where to go on this issue.

Ms. BROWNER. We will be more than happy on behalf of the administration to provide that.

[The information follows:]

*Question.* What is EPA's position on Federal pre-emption of State pesticide laws?

*Response.* The administration considered but did not include any provisions to preempt existing State and local authority to regulate pesticides as part of our pesticide food safety reform initiative. We understand many in Congress have an interest in the issue, however, and we expect it to be addressed as congressional consideration of food safety legislative reforms proceeds.

Mr. GUNDERSON. Thank you.

The CHAIRMAN. Mr. Chairman, may I ask the chairman to allow the gentleman a couple minutes, and he would yield to me?

Mr. STENHOLM. Without objection, Mr. Chairman. You can do anything you want to.

The CHAIRMAN. Well, the gentleman has touched on a point, Dr. Kessler, that I wanted to ask your expert opinion.

When you get aspirin or Tylenol, it recommend that it not be used for children under 12. Almost everything has a limitation for children under 12. Is there a specific reason for that?

I know that this is mixing subjects, but I wanted to know what is the process, or why children under 12?

Dr. KESSLER. As a pediatrician, let me try to answer that. The real problem is that no one submitted the data. Under the statute, we cannot require a drug company to test a drug for use in children. They can submit an application with the data for adults. I mean we do everything possible. I jawbone; I beg; I cajole, please do the data, because I want to know.

Aspirin, in certain instances, for children with juvenile arthritis—I mean that kind of data is very important to have. But we don't test the drug. We are at the mercy of those who submit the application and, under the statute we evaluate it.

So it is not that there is anything—I mean it is a lack of data. That is the answer.

The CHAIRMAN. So how do you get that on the label—not to be used by children under 12?

Dr. KESSLER. Aspirin we need to be careful about just because there is—

The CHAIRMAN. Similar items have that.

Dr. KESSLER. Because there is the issue of Reye's syndrome with regard to aspirin and children. But if there is no data, if it has never been tested, if I don't know the right dose, how can we give instructions for use? I can't give adequate directions for use if I don't have the data.

So in the absence of having the data, of knowing how much to give, if no study is being done, we put the information, unfortunately, "not to be used," because we don't have the data.

Before we allow it to be used, I mean we certainly don't want any harm to occur. So that is why we do it that way.

Ms. BROWNER. Mr. Chairman, if I might build on that in terms of the issues that are before your committee and this subcommittee.

It is precisely for those reasons that we want to make sure that we get the specific data as it relates to children, so that we can make sure that we are dealing with the unique sensitivities of children.

I think there is general agreement in the scientific community as represented in the National Academy of Sciences' report that there are factors affecting children, that children are different, they are growing differently, their body weights are different, for a number of reasons exposures affect children differently.

And that is why we are requesting that the law be changed to require us to specifically look at children, give us the information so that we can assure parents that their children, being the most sensitive people in the population are, in fact, being protected.

It sounds like that is not what is available in the case of the warning labels on across-the-counter drugs. But that is what we

are trying to address here in the proposal that we put forward, those very concerns.

The CHAIRMAN. Certainly the most precious resource we have is our children. I don't think anyone would challenge that. But I am concerned now that you have no authority and I don't know that we can legislate in this committee in that area.

But we could work with you. But the thing is, can we determine what is different between a farm product and a bottle of aspirin. Could we not work backwards, using the National Academy of Sciences' report and other information, work backwards so that you would know at what point children might be affected differently than someone else?

Ms. BROWNER. That is exactly the kind of information that we want to make sure we have so that we can assure the parents of this country that we are doing everything we can with respect to the children. I mean it is that kind of information that will allow us to say as it relates to children, here is the safe level.

The CHAIRMAN. Dr. Kessler, I think I am about to be shocked by what you said. You mean that it says not to be used by children under 12, but who put that there? Who made the label have that?

Dr. KESSLER. We review the label. The label gets submitted by the manufacturer for our review. And in the case of over-the-counter drugs, that labeling instructions are part of what we call monographs.

Again, it is there because no one has done the studies in children under 12. If there are studies, if there are data so we know what the right amount of drug is and we know what the safety is in children, I mean then, in certain instances where those studies have been undertaken and—you are right, I mean there are only—I mean there are not that many, unfortunately.

If, in those cases, you don't see that, you will see specific instructions. As a pediatrician, in many instances I am flying blind because the manufacturer has not undertaken the studies in kids. If you could help us in this regard—as you said, we belong to everyone; and it is an enormous problem, and it is something that I certainly would welcome the opportunity to talk to you.

The CHAIRMAN. We would like to do that because my major concern is that there you are, flying blind, if I might use that term.

Dr. KESSLER. Just as a pediatrician I end up that way, because I don't have the information or the best information.

The CHAIRMAN. But then we here are going to be asked to accommodate for children somehow, which we want to do. But it doesn't coincide with what you do. So somehow we have to get it together.

Dr. KESSLER. The National Academy of Sciences' report that was issued earlier this year is a very thoughtful, comprehensive approach to how data should be collected and the kinds of studies. That really is what the NAS report does. And I think with regard to the pesticide issue, we are in full agreement that those recommendations really need to be thoroughly and seriously considered.

Mr. ALLARD. Would the chairman be willing to yield on that?

The CHAIRMAN. Yes. Be happy to.

Mr. ALLARD. If I get the gist of his question, how did you come up with 12 years? We have had legislation that has defined chil-

dren as old as 30 years old or maybe 18 or 14 or 16. So how do you come up with 12? Because if you are talking about the impact of length of exposure to children, that age can become a difference. It may mean the difference of 12 or 18 years, for example.

So could you respond to how you would come up with that age requirement? In this particular instance he was using aspirin. But how would you define children as it applies to insecticides, for example?

Dr. KESSLER. With regard to the issue of 12 is whether there has been study and evaluation of the drug in patients. I mean if it says "do not use under 12," that means that there were patients over 12 who were part of—

Mr. ALLARD. Yes. I understand that. But how do you define the age of children?

Dr. KESSLER. It is very interesting. Because, as a pediatrician, some hospitals—when you come into the emergency room at some hospitals—when do you go to the pediatric floor and when you do go to the adult floor, there is nothing I was trained for, no expertise that I have, that solves that one. It is an arbitrary number at some point.

Mr. ALLARD. That's my point.

The CHAIRMAN. My first question, again is, we are at the mercy of the manufacturer to put on the label "not to be used by children under 12?"

Dr. KESSLER. Yes, Mr. Chairman. We are at their mercy because there are no data that allow the safe use of that drug in children under 12.

The CHAIRMAN. You are the one that I suppose sets the data that is needed for your approval?

Dr. KESSLER. Right.

The CHAIRMAN. Why don't you include children?

Dr. KESSLER. We have taken many steps to try to create incentives for manufacturers to come in with that data. I don't have the statutory authority to require them to come in with an indication for children per se. I do have the ability to try to create incentives.

And we have, in fact, narrowed the amount of data that we require. So it becomes much easier. And we have just issued a policy that says just help me get the right dose so I know how much children should take and you don't have to do all the testing again, you don't have to repeat every aspect of all the complicated drug testing that you do, just do specific parts. So we have tried to—we have pushed as far as we could push within our statutory authority.

The CHAIRMAN. I would be happy to join you and go to the appropriate committee and ask that you be given that authority. Because, again, children are our most precious resource. Our concern here is going to be with farmworkers, for example, who work in the fields. Many times children work in the fields, and heaven knows it is difficult enough to work as a farmworker. This committee has endeavored to do everything we can to see that there is a degree of protection and information for the farmworker.

We need to do that. But if you don't have authority in that area, and we crisscross jurisdictions, how do we ensure it is handled properly in the area that we will be dealing with?

And I also wanted to mention, off on the side, that I don't know at what point you decide pediatrician or a general practitioner. But he mentioned, what determines the age of children—I know some that are in their 60's who still ride the merry-go-round.

I thank all of you again.

I thank you, Mr. Chairman, for imposing on more time.

Mr. STENHOLM. Thank you.

Mr. Dooley.

Mr. DOOLEY. Thank you, Mr. Chairman. Through the course of the hearings that Mr. Stenholm has had on this issue in the preceding months here, a lot of attention was given to the testing protocols that go into determining what is the level of risk. And it was heartening to hear when the National Academy of Sciences—when some of the people that were directly involved with that testified here that they were almost universal in their agreement that the testing protocol or the concept of maximum tolerated dose has some inadequacies in it. It might be the best available at this time. However, they were very supportive of moving forward with trying to determine if we can develop and adopt a better testing protocol.

I am wondering if the interagency task force has considered this issue and if it is also supportive of trying to determine something that can give us a more accurate estimation of the risk.

Ms. BROWNER. We are continuing to—we always review the science in some ways that we use because it does change, and we work across the scientific disciplines, in terms of hearing from all of them and putting in place the mechanisms we have for evaluating the science that is presented to us and then for the decisions that we make.

The agency also uses scientific peer review panels, to make sure that we get a broad look. But I think we agree with the academy that this is an evolving area of science and that we want to be able to take advantage as an agency of that evolution and make sure that we are incorporating the very best.

And in some of the instances in terms of what the academy recommended, I think they now agree that the science we are using is the best. In other instances, quite frankly, the agency and the scientific community are working to develop the scientific tools, because it is the cutting edge science that we are, in fact, going to look at some of these issues.

Mr. DOOLEY. I guess that is my concern. Even when you are looking at trying to assess the impacts on children, you are adding even another variable when you move from the animal studies and to extrapolate back.

And I guess some of us think that there needs to be almost a directive issued by the administration to work in a coordinated fashion with some of the international bodies to try to see if there isn't a better way to develop these testing protocols.

Ms. BROWNER. We do work very closely around the world with other agencies, with other governments, in terms of the work that they are doing in developing these testing protocols. We are very active in the international pesticide issues and in science, that is occurring.

We also—to go back to your earlier question—there is, I think, a real opportunity in this administration for working across the

three agencies on this. I think, as you have seen today, we each have a slightly different piece of this; but the reality is, it only works for the farmers, for the children, for the people of this country, if we can work together. And that is, I think, being clearly demonstrated here today; and it is something we are all really committed to continuing and making sure that it continues down into the agency.

Mr. DOOLEY. I have a question about the phaseout of consideration of benefits. I introduced a public health pesticide bill.

When we have a product that is used to promote public health that might be determined to have some risks that might either exclude this negligible risk standard that the administration is proposing, yet it still has tremendous benefits in terms of alleviating some other public health consequence which is a benefit, are you saying that after 5 years we are going to give no consideration to that benefit?

Ms. BROWNER. The proposal would allow for a 5-year extension. At the end of that 5-year extension, if the pesticide tolerance exceeded the standard, there would be a 5-year extension.

If the tolerance could not be brought down to within the negligible risk standard, and in many instances we are able to work with the manufacturers, with the farming community, to reduce the risks, that if that were not possible for some reason, then it would take an act of Congress to allow the continuation of that use.

Mr. DOOLEY. Mr. Rominger, with regard to the administration's call to have 75 percent of our acreage being IPM by whatever year it was, being a farmer in California, who has really been using IPM for the last 20 years, and has been monitoring pest populations and predators as well as beneficials, I am wondering how are you going to define what is IPM?

And I guess that also relates to another issue in terms of moving forward and trying to provide some incentives for the utilization of environmentally friendly or safer alternatives. How are you going to define those?

And, as the last question, are we, in fact, going to put in incentives for these environmentally friendly alternatives and biologicals to work in terms of the registration process or with certain timeframes that can provide some assurance to the people who are developing these materials?

Mr. ROMINGER. To answer your last question first, yes, we do have some incentives in this proposal for speeding up the registration process—you want to call them safer pesticides and for biological pesticides.

So we believe there will be some incentives there, and Administrator Browner can expand on that if she would like.

As far as the how do we define integrated pest management, I think there are probably a lot of decisions—or a lot of definitions of that. But I think we can agree on the kinds of things that you talked about that farmers are using.

We think that probably 20 percent of the acreage out there now is under IPM; and, of course, in some crops that may be as high as 80 percent, for example processing tomatoes in California.

So there is a lot of activity on integrated pest management. And I think by looking at the new technologies, whether they be biologi-

cal controls, the beneficial pests, cultural practices, we can look at what is happening on the farms and determine whether or not they are using an integrated pest management plan.

Mr. DOOLEY. The definition of safer alternatives in pesticides, or however you want to refer to them, that you are going to give expedited registration, how are you arriving at that? Is there some criteria in your proposal?

Ms. BROWNER. I think that is something that would be absolutely appropriate for discussion between the subcommittee and the administration.

The goal is to do everything we can within the registration program to make sure that safer alternatives are available to the farmers in a timely manner. There is the opportunity, and we will give time-limited tolerances for the biologicals that we know are safe, based on experience so that those will be—the farming community can continue their use where appropriate.

But I think in terms of defining what safer alternatives and how EPA would manage its workload, that is a conversation that we would be very interested in engaging in.

Mr. ROMINGER. I think we would work with the committee to develop that. And we proposed to define safer through the rule-making process.

Mr. STENHOLM. Mr. Allard.

Mr. ALLARD. Thank you, Mr. Chairman.

Administrator Browner, I would like to follow up a little bit more so I am clear in my mind.

Everybody's clear about some of your sunset deadlines as they apply to registration. Now, the original end date that was scheduled for reregistration of pesticides under the 1988 amendment—what was the original end date on that?

Ms. BROWNER. 1997.

Mr. ALLARD. 1997. And then what is the present schedule end date for reregistration of pesticides?

Ms. BROWNER. Well, we are doing everything we can to try and meet the 1997 deadline. We are working as hard as we can. I am not suggesting that in the end we are going to be able to do that. We recognize that there are concerns in the reregistration program.

Again, I think part of the problem, Mr. Allard, is that the system, the process of reregistration, has been very cumbersome for the agency; and that is why we are seeking changes.

Mr. ALLARD. And so I have heard estimates of it might be up to 2015 or so on some issues. Would it be that long?

Ms. BROWNER. No, I don't think it would be that long.

Mr. ALLARD. What is the maximum that you have?

Ms. BROWNER. But, again, the agency—

Mr. ALLARD. What is the maximum that you have, that you would see?

Ms. BROWNER. The outer limit, based on our analysis of the work before us, is 2003.

Mr. ALLARD. 2003. Now, how many times has Congress been informed of a new or more distant end date for reregistration?

Ms. BROWNER. Mr. Allard, I have been in this job for 9 months, and I have given that answer since I have been here. I don't know

what happened before that in terms of whether the agency provided different information.

Mr. ALLARD. I think it has been several times, according to my information.

Ms. BROWNER. That may be. Yes.

Mr. ALLARD. And so how many chemicals have we reregistered to date?

Ms. BROWNER. Of the 400, 40.

Mr. ALLARD. Forty. And I have 31. So we are in the same ballpark.

Ms. BROWNER. I think we have done some more.

Mr. ALLARD. So what you are doing is, with your sunset provisions, you are coming down to a 3-year period?

Ms. BROWNER. Fifteen years.

Mr. ALLARD. Fifteen years?

Ms. BROWNER. I think this is in the registration, not the tolerance. It is in the registration. It is a 15-year sunset review. And it would be triggered off the date of reregistration. So we wouldn't have everyone on the same 15-year cycle.

Obviously, that would be an incredible workload for the agency again. The point is to correct what is wrong with the current system.

Mr. ALLARD. So are you allowing 3 years for just the review of the reregistration data?

Ms. BROWNER. Once during the 15-year period, the information has to be submitted in the 12th year so that the agency has 3 years before we come to the 15th year to complete its review.

Mr. ALLARD. To review that.

Ms. BROWNER. But, again, everyone we——

Mr. ALLARD. And then you have a 1-year grace period.

Ms. BROWNER. If the agency fails to act and all of the information has been submitted, then there is a 1-year grace period.

Mr. ALLARD. Which may extend it to 16 or so. It is 3 years plus 1 more within the 15?

Ms. BROWNER. I see. The 15 plus 1 more. You are correct, yes.

Mr. ALLARD. Now, the problem that you are having with this extended reregistration, do you think it is a technological problem or it is difficult to get the scientific data within that time period?

Do you think it is a procedural problem where applicants are asked to continue to provide more information and then that sets everything back? Or is it a manpower problem, you just don't have enough people to get it done?

Ms. BROWNER. I think it is a combination. It is obviously a very expensive process. We have had considerable difficulty in getting the information submitted in a comprehensive form when we start the process. And some would say that what that leads to is couldn't EPA ask for more information initially. That is one way you could look at it.

We look at it in a slightly different way, which is we didn't get the information on the front end; so we have to keep asking. That doesn't work for anybody, regardless of what creates the problems. I think we can all agree there is a problem, and the point is to get the information we believe that with the 15-year sunset, that the manufacturers, the producers of the chemicals, will be strongly in-

clined to provide us with all of the information in a timely manner. And that has been a very significant problem for us.

Mr. ALLARD. And does your agency know what that information should be? And do you ask that ahead of time?

Ms. BROWNER. Yes.

Mr. ALLARD. They just don't follow your instructions? Is that the problem?

Ms. BROWNER. Right now there is no inducement. There is nothing to ever cut it off in terms of getting us the information. It can drag on because the chemical can continue to be used while this whole reregistration process is churning along. This would put in place clear deadlines in terms of the submittal of the information that we need to make a decision.

Mr. ALLARD. But the information I got from your testimony is you are willing to work with this subcommittee in addressing our concerns on this reregistration, your sunset provisions; is that correct?

Ms. BROWNER. Yes.

Mr. ALLARD. I have a question, Dr. Kessler, on the studies on cancer with children. I would think your results on that would be long term. It may be 60 years before you know that. I mean you may get—would you—are you looking—are you thinking in terms of the results on—acute toxicities are no problem. But if you are talking about a cancer-causing problem, you may get exposed to 30, 40, 60 years before you notice a changing incidence in cancer. Looks to me like it is going to be a long time before you get results from that type of study.

Are you looking at a long-term study like that?

Dr. KESSLER. The difficulties that you just cited, the reasons why we have to go to—that we have gone for the last 20 or more years to animal bioassays, that we know by definition are imperfect. Because even the best designed epidemiological studies are not going to be able to have the kind of power to determine whether certain food substances, do or do not cause cancer. We don't have the science there and certainly can't do the human control kind of trials to answer those. That is why we go to animal bioassays.

Mr. ALLARD. But so in terms of children, on an animal study, how are you going to differentiate the difference between adult and children?

Dr. KESSLER. Well, what the best of the methodology today does, what the quantitative risk assessment is all about, is to first understand—you have to understand what children consume.

And we are saying today that we need to improve our understanding of that data base. And that allows you to calculate what kind of exposures the children have to certain kinds of chemicals.

So you have that data point, and you understand that exposure. Then you use your animal bioassay to determine what the risks are at different exposure levels. And that involves certain extrapolation.

So it is a combination of using data, that is derived from actual human experience and the animal bioassays; and that is what the risk assessment methodology that we are advocating moving toward and away from the strict applicability of Delaney, in the case of pesticides, really entails.

Mr. ALLARD. And you are comfortable with the transference of data on animals to children?

Dr. KESSLER. Am I comfortable? It is the best that we have available today. It has improved dramatically over the last 20 years, our methods of quantitative risk assessment. The NAS points out that in animal studies of in utero exposure to carcinogens and getting that data, we do do that in certain instances already now at FDA, but moving more to include those kinds of tests. Those would be valuable. Are they perfect? No. And unfortunately there are gaps. There is no foolproof test to know exactly what is not the human carcinogen.

Mr. ALLARD. Thank you.

Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Volkmer.

Mr. VOLKMER. Yes.

I guess I could start off with Dr. Kessler by telling one of my first experiences as a Member of Congress was back when one of your predecessors, Dr. Kennedy, proposed the ban of saccharin. And my work on that leads me to one experience where I am today and looking a little aghast at some of the things that have been done in the past, are supposed to do in the future as far as food supply and additives to food.

I, Ms. Browner, will not revisit the question of the gentleman from Wisconsin and the gentleman from Colorado on the reregistration, because I go back, again, here since 1977, as your former boss was, and well remember traditional registration and requirement registration and where we are today.

And then I look at what you are asking as far as tolerances. You are now asking for a 7-year program on all tolerances. What if, even if the 1 year is given with the added year but everybody has all their data in, what happens in the ninth year? You haven't improved tolerances on all of them.

Ms. BROWNER. I apologize. I think you are confusing two issues. The 1-year extension relates to the registration.

For tolerance, there is a 5-year opportunity for an extension.

Mr. VOLKMER. All right. There is 5 years on 7 years?

Ms. BROWNER. Let me see if I can walk through this quickly. There are 7 years. The information must be submitted within 7 years in terms of the use. The information must be submitted by the applicant at the end of 5 years.

The agency has 2 years to do its review. We believe we can do that job in 2 years. If there is a finding that the use exceeds the negligible risk standard and the benefits in terms of a disruption in the food supply are severe, then there is the opportunity for a 5-year extension while the applicant works to bring that use down to the negligible risk.

At the end of that time, a timeframe not to exceed a total of 10 years from the date of enactment—so it would encourage people to come into the system more quickly to provide us with the information—there are numerous mechanisms in our proposal to get us the information that we believe will allow us to work in the timeframes that we are recommending to Congress.

I want to say something just generally about the Environmental Protection Agency. We are subjected to a number of deadlines in

terms of how we do our job. You have my commitment that I will tell you how much time we honestly need to do something and that we will not try and suggest that we request something in a timeframe that we will not be able to meet. We will explain to you the resources we need to meet that commitment within that timeframe.

We have looked at this, and we believe with the proposals, in terms of the inducements for getting the information to us, that we can deal with the tolerance issue in that timeframe. On the registration issue, the reason we are suggesting the 15 years, speaks to what we think it will take us to do the job.

Mr. VOLKMER. All right. On the tolerance, how much of it are you doing today that you will be doing when the law is enacted?

Ms. BROWNER. We handle the tolerances now. That is our responsibility. There are 9,000 food use tolerances established today; 600 chemicals, 9,000 food uses.

Mr. VOLKMER. How much more do you anticipate? Are you going to have to revisit the full 9,000?

Ms. BROWNER. We anticipate that we can do about 70 to 80 percent of that in the first several years, that we will be able to move very quickly through a large number of them early on.

If the question is: Do we anticipate that the number of tolerances, 9,000, will significantly increase? I don't think we do.

I think that that is considered to be about where it will continue. It may go down, it may come up slightly; but that is a realistic number.

The issue has come up about the 1,400 tolerances that have been discontinued. In many instances, what has happened is the registrant was not interested in continuing the tolerance. They didn't pay the fee, when the fee program came into place; and, therefore, it was not continued. It wasn't because the agency said it wouldn't be continued. It was because the registrant made a decision in terms of the use.

Mr. VOLKMER. Well, the reason I ask all this, because I envision a part of your problem—part of your predecessor's problems has been doing everything in 11 and 7 years, that was anticipating in answer to one of the questions, you said it was part of the problem, manpower, dollars to do the work. And I have seen in the past, that we in the Congress have given EPA additional responsibilities, continued additional responsibilities with EPA in the past that has said they are going to be able to do; and then we don't give them the dollars to do it with, the Appropriations Committee doesn't give them the dollars to do it with.

And I want to make sure that you are going to be able to do it without the dollars. Because I don't think you are going to get the dollars.

Ms. BROWNER. We agree that that has been a problem for the agency in terms of having the resources that we need to do the job and in the timeframe that Congress has asked us to act.

The administration's proposal does include a reregistration fee. We think that would give us the money that we need to allow us to have the manpower.

Mr. VOLKMER. That is on the present reregistration program.

My time has expired, Mr. Chairman. I would like to know if we are going to go another round or if I could ask for 2 minutes. I have another subject matter.

Mr. STENHOLM. We will go another round. And I would prefer we allow each member to question in the first round. We are going to have to be out of here in time for a full committee mark-up here at 1 o'clock. So that is our time restraint. Ms. Browner.

Ms. BROWNER. If I could just finish on that.

Mr. STENHOLM. Finish answering the question.

Ms. BROWNER. We will provide all this to your office in writing. Our calculations show about a \$20 million shortfall in terms of the resources we need to do the job.

And we can show the reregistration fee that we are talking about in terms of how we would meet that shortfall. The President's EPA fiscal year 1994 budget request did seek an increase for us in this program area so that we could meet our goals. At least temporarily within the agency we will try to make some allocations that will allow us to put more people on to this program, because we do recognize the severe nature of the workload and our responsibility.

The fundamental issue in the reregistration program is that we are trying to do an awful lot in a relatively short period of time. We are essentially dealing with a lot of pesticides that have been on the market since World War II in some instances; and we are taking all of them and saying reregister all of them at the same time. It is a huge undertaking for us.

And we can talk about how it would be structured and I think we would look forward to how we can set this up for the future so that we don't have this logjam again and again and again which causes a lot of mistrust; it causes a lot of misunderstanding.

I don't think it is helpful to any of the people that we all care about, whether it be the farmers or the consumers.

Mr. STENHOLM. Mr. Smith, just briefly.

Mr. SMITH of Oregon. Mr. Chairman, thank you.

Would the three witnesses accept written questions from this subcommittee and respond as soon as possible to them?

Some are not here. Some of the members may want to offer questions to you.

I thank you.

Mr. STENHOLM. Let the record show all three heads were shaking.

Mr. SMITH of Oregon. Thank you, Mr. Chairman. From my point of view, the question was raised about a bill to be written by the administration. I have been a part of this subcommittee when another administration was attacked because they didn't have a bill before the subcommittee that could be ripped apart. My purpose is not to embarrass this administration. My purpose is to get a quality product. I would prefer that you not offer a written bill, so that that would give us maximum flexibility; this subcommittee is flexible. I would hope that you would be. And we could work this out together, from my own opinion, Mr. Chairman.

Mr. STENHOLM. Mr. Ewing.

Mr. EWING. Thank you, Mr. Chairman.

Ms. Browner, my first question is: Have we established beyond any reasonable doubt that our current system of monitoring and approving pesticides is totally inadequate?

Ms. BROWNER. If you are speaking to the reregistration program, Mr. Ewing, I think we would all agree that it has not been everything that it should be or could be.

Mr. EWING. But have we been able to tie to the way we are doing it many of the health problems, such as cancer, in this country? Or are we just thinking that is out there, and so we are going to redo this program?

Ms. BROWNER. I think, as the National Academy of Sciences pointed out in their report issued in June, which is the most recent report looking comprehensively at—or at least as it relates to kids and infants—that we do have a safe food supply in this country. There are things that we can do to make it safer. There are things that we can do to protect farmworkers, to protect ground water, to protect drinking water supply, the children in the parts of the population most at risk, we need to be extra careful to make sure that we are doing everything we can to protect them.

And that is what we are here today proposing, that we make sure that we are taking advantage of every single opportunity to continue to have the safest food supply in the world.

Mr. EWING. And we all want that. But there does come a time when the cost-effectiveness is lost and you can't get a whole lot safer.

And thank you for saying that we do have a safe food supply, because I believe we do in this country.

You talked in your comments several times about children. Are we going to have one study for children and one study for the rest of the American population?

Ms. BROWNER. What the academy recommended, which is what we are proposing to Congress in terms of legislation, is that we do look at the unique factors affecting children. And they set out several of them.

We do, in some instances, already do that. There are others that we are moving to do. But we would ask that the legislation include a requirement that EPA make a specific finding as it relates to a tolerance, the effect on children, and make sure that we are doing everything we can to protect children.

Mr. EWING. Was the answer yes or no?

Ms. BROWNER. Well, there would not be two tolerances. That is not the point, as I said earlier, there is the fruit for the adults and the fruit for the kids. I don't think that is in anybody's interest, the farmers, the processors, the grocery store owner.

The point is to make sure that in setting a tolerance, we are accounting for those who are the most sensitive part of the population, that they are protected with that tolerance. We believe, in many instances, that is the case. The point is that we would make a specific finding and so the public would have that assurance.

Mr. EWING. If you did that for children, there wouldn't be the necessity of doing it again for adults.

Ms. BROWNER. The information that would be submitted from the manufacturer seeking the tolerance would have to include information specific to children. And that is what this would change,

that we would get specific information relating to children and that the agency would be required to take that information and look at the other exposures that children may experience beyond this particular pesticide use on this food and make sure that all of that has been accounted for and that the children will be protected.

Mr. EWING. Coming from a feed grain area of the country, I wonder, are corn and soybeans that we feed to our livestock going to be judged by the children's standard or another standard?

Ms. BROWNER. To the best of my knowledge, corn and other commodities fed to livestock do not have a food use tolerance associated with them because they are not for human consumption.

Vic Kimm, who is the Acting Administrator for this program, reminds me that there are rare instances where there are tolerances for feedstock, because the feedstock carries through to the human's diet.

So there are. But they are apparently fairly rare.

Mr. EWING. Well, if you have to meet those tolerances, does that mean that all the feed grain—we don't know whether a field of corn is going—just where it is going, from ethanol to corn flakes to livestock feed?

Ms. BROWNER. Well, for those, as I understand the way the farmers deal with the situation is, if they are not aware of where their crop is actually going that they then make sure that they are operating in accordance with the food use tolerance.

Mr. EWING. With the highest standard then?

Ms. BROWNER. Right. The most protective, right.

Mr. EWING. How much additional Government bureaucracy or employees do we anticipate needing for your agency to carry out this type of a mandate?

Ms. BROWNER. Actually, we don't anticipate a huge increase in the Government bureaucracy. Quite the contrary. We believe, by staggering the registration with the sunset as opposed to making us do everything at one time, that there are efficiencies that that creates.

We believe by requiring the information to be submitted in certain timeframes and certain formalities, there are efficiencies that are created. We do agree that we do not have all of the resources that we need to do the job right now, and that there would need to be more resources available.

But this is not a huge bureaucracy. That is not the point here, to create a huge bureaucracy. The point is to make sure that the food is protected and that we are responsive to the needs of the farmers in giving them the answer so that they can farm and move their product to the supermarket or, in your case, move the grain to the feedstock.

Mr. EWING. I thank you for your answers. One of the points that I think we need to make is that what we put in place here must be responsible and reasonable and something we can afford to do for the benefits we will obtain from it.

Thank you.

Mr. STENHOLM. Mr. Inslee.

Mr. INSLEE. Thank you, Mr. Chairman. I appreciate your testimony, Ms. Browner. And I am sorry I had to miss some of it.

Let me ask you, when we talk about the 5-year—I will call it a grace period, if I can—when we find that there is something over the negligible risk standard and then we look at the potential disruption of the food chain, one of the things that we have found in my community is that when we have lost certain pesticides, it has made it more difficult for us to go to a IPM process because some of the minor pesticides we have lost were very important in a IPM situation.

Can you envision that problem being something that would justify the continuation of a grace period?

In other words, you have something that is over the negligible risk standard, but it is important as one tool in the IPM project; is that the kind of thing that you envision could qualify for that grace period, if you will?

Ms. BROWNER. Well, let me just back up for 1 second and say that the whole reason that we have suggested a transition period is to deal with the very type of situation you raise, which is what happens if something were to be removed immediately and the effect it may have as opposed to allowing the manufacturers, the farmers, the producers, et cetera, to start to prepare for the change, to allow for a transition.

I might let Secretary Rominger speak to that from USDA's perspective; but that is why EPA has thought that a transition was important so that we could make sure that there was the opportunity for alternatives, for the integrated pest management to be clearly put into place.

I know that our people believe that 5 years is a timeframe that allows for those things to occur, that the market does adjust rapidly in terms of changes in the chemical production or integrated pest management.

But I don't know if you wanted to——

Mr. ROMINGER. No.

Mr. INSLEE. I want to ask about what drove you to the decision to require a sunset, if you will, of all existing registered products.

And I am real curious of what led you to the conclusion that that is a prudent investment, as opposed to some alternative investment of public funds, for instance, developing IPM products and procedures and strategies, dealing with our *E. coli* problem.

The reason I say that is that when I look at all the risks in the food chain, at least in my view, going back through the registration process and assuming that we are going to find additional dangers just because of our technology and being able to identify them, what led you to that conclusion? Don't we already pretty much know the risk factors of these products?

Ms. BROWNER. Well, first of all, as I think we would all agree, there has been tremendous frustrations with the reregistration program. And so in looking at that program; looking at what the agency wanted to do; what was expected of the agency; we want to propose to Congress changes that would allow us to meet these expectations.

With the 15-year sunset, I think it is important to understand, we don't go back and look at every single thing every 15 years. We would only look at the new information. And there is changing in-

formation. I mean this is an area of science that is evolving. There are changes in terms of how the farmers are doing their job.

And so this would allow us to look at the new information. It would not be our intention to look at everything we had already looked at previously but rather, if there is new information, to look at that new information, to take it into account.

It requires the manufacturer of the chemical, of the pesticide, to bring us that new information so that we can evaluate it.

Mr. VOLKMER. Would the gentleman from Washington—on this area, if I remember your statement, the reregistration of a new pesticide only has to do with the active ingredients, does it not? Not the original pesticide, but the active ingredient.

Ms. BROWNER. Precisely, thank you. Yes.

Mr. VOLKMER. All pesticides that incorporate that active ingredient. So what you would be doing is looking at the active ingredients that are contained in these pesticides, multiple ones, and they would all provide you with data; is that correct?

Ms. BROWNER. Reregistration is by active ingredient; that is correct.

Mr. VOLKMER. Right.

Ms. BROWNER. It carries on to the product.

Mr. VOLKMER. Everybody that is using that active ingredient in their product would be asked to bring forth the data; is that correct?

Ms. BROWNER. I think this is something that it would be helpful to talk about at that level of detail, perhaps between our staff. I think this is not insurmountable in terms of, perhaps, the concerns that we are going to be looking at everything. That is not our intention. And you are right, the reregistration program does focus on the active ingredients.

Mr. STENHOLM. Mr. Inslee.

Mr. INSLEE. Thank you. How do we have a guarantee for the kind of concerns that we have about actually being able to deliver the funding you need to accomplish this? What confidence level can we have and what mechanism can we come up with that confidence?

Ms. BROWNER. Well, two points. First of all, we are in the fiscal year 1994 budget, submitted by the White House for EPA. We did reallocate funds to help us increase the revenues, the resources available in this area.

This package that the administration is proposing would also ask for an increase in terms of the fees to allow us to do the job that we need to do. And we are going to provide a detail of what our needs are. As I said before, we estimate about a \$20 million shortfall as it relates to the reregistration program in terms of getting the job done.

Mr. INSLEE. Thank you.

Mr. STENHOLM. Ms. McKinney.

Ms. MCKINNEY. Thank you, Mr. Chairman.

Ms. Browner, tell me about pesticides that have been banned for environmental reasons and their export. Will we still be able to export them?

Ms. BROWNER. We ban pesticides that are not registered or reregistered in this country because of health concerns. If a pes-

ticide is canceled or suspended, then it, under this proposal, could not be exported to another country, for health reasons.

We focus on the health reasons. If it has never been in our registration system, if we are informed by another country that they do not wish to have that pesticide shipped to them, then it is not shipped.

If it has never been registered and it is being shipped to another country, we do notify that country that this pesticide has not been registered in the United States, it never started the process or it came into the process and went out of the process without completing the process of either securing a registration or denial.

Ms. MCKINNEY. So what happens then to food that has pesticide residues that are imported into this country?

Ms. BROWNER. Foods containing pesticide residues that do not meet our laws cannot enter the United States. If they don't meet the tolerances, the health standards that we have set, then those foods are not permitted to enter the United States.

Ms. MCKINNEY. Is there a loophole?

Ms. BROWNER. In terms of what we are proposing, I think it is a significant package. I mean we are open to working with you within what we are proposing as it relates to the exports of pesticides. We are open to working with you.

In terms of do we think there is a loophole in that fruits and vegetables containing pesticide residues that would not be allowed to go to market grown within the United States are entering the United States, we have every confidence that FDA is doing their job. I mean that is part of the job that they do. And we are very confident that there are not fruits and vegetables grown outside of the United States with pesticide residues that would not be permitted in the United States, entering the United States.

Ms. MCKINNEY. OK.

Ms. BROWNER. So I mean, again, if there is something that we could talk about, we would be more than happy to do that. If you believe there is a loophole, we would be very interested in understanding that so we could address that.

Ms. MCKINNEY. Thank you.

Thank you, Mr. Chairman.

Mr. STENHOLM. Mr. Allard, do you have another round?

Mr. ALLARD. No.

Mr. STENHOLM. Mr. Volkmer.

Mr. VOLKMER. Yes. I have several areas.

One, I would like to commend you on your export thing. It makes a lot more sense than the legislation that we have seen up here in the Congress called the circle of poison. At least you have some conditions on it.

There is one area yet that I still have some concern with on your proposal on that. Let's say that a manufacturer of chemicals, pesticides in this country, is approached by producers, et cetera, in another country, that produce a product only utilized and eaten in that country and that country permits the sale and use of that pesticide in their country but it has never been registered here, it has no tolerance level, will never be used here and the food will never arrive here, under your proposal, that would not be able to be sold?

Ms. BROWNER. Under our proposal, we would notify the receiving country, the foreign country, that this is a pesticide that has not been registered for use in the United States. They would have that information.

Mr. VOLKMER. But you also have not established a tolerance level?

Ms. BROWNER. Right. The tolerances don't go to the pesticide. They go to the food use.

Mr. VOLKMER. You could make a decision that it does have a risk.

Ms. BROWNER. Well, if it has never been submitted to us for registration, then we notify the country that we have not looked at and analyzed this particular pesticide.

Mr. VOLKMER. So are you saying that could be exported in? Your assumption is that that product could be exported?

Ms. BROWNER. Now if it is going to be used on a food that is going to come back to the United States—

Mr. VOLKMER. No. Never come back to the United States.

I can tell you one. How about rice in Japan? Rice in Japan doesn't go anywhere except in Japan.

Ms. BROWNER. I mean if it is not coming back to the United States, there is no tolerance.

Mr. VOLKMER. Doesn't go to Korea; doesn't go to China; doesn't go anywhere else?

Ms. BROWNER. Right.

Mr. VOLKMER. That could be sold, right?

Ms. BROWNER. If it is unregistered?

Mr. VOLKMER. Yes. Because there is no use here in the United States for it.

Ms. BROWNER. It could be sold.

Mr. VOLKMER. Thank you very much.

Now the other thing I would like to talk to you about on personnel—no, before I get to that, I have something a little more important. I commend what you are doing on the biologicals, OK, the DNA derived.

But I have, ever since several years ago when I was chairman of the INO and Science, Space, Technology, we conducted hearings on this and tried to bring USDA and EPA closer together; and I think they have been.

But as one who I think recognizes that a DNA-derived biological is not a chemical, still has problems with the fact that we regulate on a basis that it is a chemical, because that is the only law we have on the books.

Correct or incorrect?

Ms. BROWNER. I am going to have to perhaps let one of the experts on this—

Mr. VOLKMER. The only laws that are on the books—

Ms. BROWNER. If they claim that it is a pesticide, then we do regulate it as a pesticide, that is true.

Mr. VOLKMER. But on the statutes that were meant purely for chemicals.

Ms. BROWNER. No. I think that we seek to curtail the requirements to be more—

Mr. VOLKMER. Well, let me ask you this: As one who attempted to write legislation with previous administrations but they didn't want to do anything because I think they were afraid something else would work that would be more harm than good, I would like to work with both of you to try to what I call update our regulatory statutes in regard to registration, especially for biologicals.

Ms. BROWNER. We would be more than happy.

Mr. VOLKMER. I commend you for what you have done so far, even administratively.

Mr. STENHOLM. Would the gentleman yield for just a moment?

Mr. VOLKMER. Yes.

Mr. STENHOLM. When you said work with both of you, which one are you not wanting to work with?

Mr. VOLKMER. Well, the ones—only ones that really apply on the registration are USDA and EPA. FDA doesn't have anything to do with it. That is why I say "those two," which, when done with previous administrations, got nowhere. Hopefully we would get somewhere this time.

Mr. ROMINGER. We would be happy to work with you.

Mr. VOLKMER. Thank you very much.

The other thing I want to commend all of you on and the administration is the recognition that the Delaney clause is outdated, the Delaney clause needs to be brought into the present and hopefully into the future, and I wish to commend you on that.

The other area that I think we need to recognize is that as our producers out there are attempting to produce environmentally sound methods, that we have to recognize as the gentleman from Washington pointed out, that sometimes that means also the use of chemicals within that environmentally sound method technology.

And as I see more and more of my farmers going to what we call no till, if they use no till, Mr. Rominger, you pretty well have to use some herbicide; is that correct?

Mr. ROMINGER. Most of the no till now, they use a herbicide, that is correct.

Mr. VOLKMER. Use it fairly extensively. Now there are tradeoffs. If you don't use the herbicides, they are not going to do the no tills much; they are going to go back to violate the ground, watching the ground wash down the streams.

Mr. ROMINGER. Under the present culture methods, yes, that is correct.

Mr. VOLKMER. Thank you very much, Mr. Chairman.

Mr. STENHOLM. I thank the gentleman for his questions. And I concur with some of his statements regarding this. I kind of wish some of the TV cameras that were present yesterday were present today.

From what I understood, the general tenor of yesterday's hearing was considerably different than the tenor of the questioning and the responses—not necessarily the responses. But today, when you talk about the Delaney clause, I hope that everyone understands that it is technically impossible to reach zero tolerance concerning carcinogens in our food supply. And, therefore, some of the sensationalism that goes with this and some of those who believe that somehow proposing to change Delaney is something that we could accomplish and leave it alone. I constantly have a problem with

those that do not recognize that over 98 percent of the known carcinogens in the world today God made all by himself.

That gets into Mr. Ewing's question concerning the tolerances for food. And I think the three of you recognize that this is a very complex subject that we are undertaking and one in which there are no simple answers; and certainly one of those answers is that zero tolerance for carcinogens is not realistic. It is impossible to reach. And, therefore, we have to have a rational discussion of this. And it needs to be rationally put forward to the general public so the general public will understand that those voices among us that say that we must maintain Delaney, it is impossible.

And I will defy anybody to pass legislation that will keep 100 percent carcinogen-free food in front of the general public. It cannot be done.

Mr. VOLKMER. Will the gentleman yield?

Mr. STENHOLM. Be happy to.

Mr. VOLKMER. In that regard, I would just like to pose a question, not necessarily to answer, just something to think about. Because I have over a period of years, ever since the saccharin episode, Dr. Kessler—and that is from what I learned at that time as regard to our food supply and what the gentleman from Texas just said about the naturally occurring carcinogens, what if we applied the new risk, negligible risk, or whatever, not only to additives but to all food?

Do you want to make a comment now, or do you want to send me one in writing? I would like to know. Because right now it is just additives.

Mr. STENHOLM. I assume they will respond to your office in writing to that question. Let me ask a couple of other nonrelated but relevant questions for you today. Just as the gentleman saying, "work with two of you," I would amend that a little bit Harold, in saying that I think the spirit of cooperation we are seeing here today even in areas we have traditionally thought in terms of not being related, we are going to find the three agencies working together in resolving the questions in the future.

In that light, Mr. Rominger—and I do not request an answer necessarily for this—but in regard to the reinventing Government, right now the Department as you are aware is about to promulgate a rule that requires all raw ground meat and ground poultry packaging to contain new handling instructions by October 15.

All other raw meat and poultry products would have to come in compliance by January 15. In February, meat and poultry processors must add metric weights to all of their packaging as well as traditional American pounds and ounces. On July 1, they must add nutritional information on all packaging. This plan could require processors to change their packaging four times in less than 9 months. And I just have to believe that you are considering this statement and this request in this.

I would not have wanted to miss the opportunity again to suggest that everyone seems to be able to meet the October 15 deadline on raw ground meat and poultry and we understand why. Given the tragedies that we have had, we understand why we must meet this deadline. But also in the spirit of reinventing Government and the spirit of entertaining unnecessary cost, we hope that

we—that you will be able to withstand perhaps some of the pressures for doing too much, too soon, without a common sense application as you have testified today in regard to the overall question of pesticides, FIFRA, et cetera.

Mr. VOLKMER. Will the gentleman yield on that?

Mr. STENHOLM. Yes.

Mr. VOLKMER. I would like to join, Mr. Rominger, with the gentleman from Texas on that. Because just using common sense, if we could do all of this at one time, say in June of next year, and the processors can all do it and bring it all into that one label, it makes a lot more sense than going through labeling changes three times between October. You have to do the first one in October. After that, doing three more by June, why not just do one. And I don't think the American public really is going to be injured that much.

Mr. ROMINGER. Certainly be happy to take a look at that and see where we are.

Mr. VOLKMER. Appreciate it. Because we love common sense.

Mr. STENHOLM. Regarding minor use, is the proposal you have brought to us today essentially a duplicate of Chairman de la Garza's H.R. 967? Or are there any differences?

Mr. ROMINGER. I think we have taken most of the things in Mr. de la Garza's bill and included them in our proposal. I am not sure that we have everything.

Mr. STENHOLM. What funding would you propose for IR-4 and for public health pesticides?

Mr. ROMINGER. For IR-4 in the 1995 budget request, we will be requesting full funding, which I believe is \$14 million.

Mr. STENHOLM. What about the public health pesticides? Are nonag uses, for example, nursery and turf, covered in the definition of minor use?

Mr. ROMINGER. Yes.

Mr. STENHOLM. Final question today. I preface this in the same way I did the previous question. Not necessarily totally related to FIFRA but in the sense that we are going to be talking about clean air, clean water, et cetera, going back to the question on methylbromide.

As I understand it, methylbromide is classified as an ozone depleter. Yet it is argued that methylbromide is essential to agriculture, that there are few if any alternatives for farmers and that the science on methylbromide as an ozone depleter is shaky.

Now, Mr. Rominger, in the event methylbromide is banned, has the Department looked at an alternative?

If so, what are you finding?

Mr. ROMINGER. Two things I would like to say. First of all, that the scheduled phaseout or ending in the year 2000, in the interim the United Nations Environmental Committee is doing an extensive review on the determination of how extensive an ozone depletion chemical it is; and the results of that study will be looked at before a final determination is made that the phaseout takes place in the year 2000.

Second, in the alternatives, we are dedicating research money at USDA in looking for alternatives. We have had a nationwide conference on alternatives for methylbromide; and so we are exploring

all the possible avenues there. We have \$1 million in the budget for the coming year, looking at—for doing research and alternatives for methylbromide. So we are certainly looking to see what is available.

Mr. STENHOLM. But right now, there is nothing available or—

Mr. ROMINGER. Right now there is nothing comparable. The alternatives are not as good.

Mr. STENHOLM. My concern is that many in the scientific community are suggesting, perhaps not publicly, that it may be a little early to draw conclusions about this question. And I believe you have indicated that.

And I want Ms. Browner to comment on this also, that with the United Nations taking a look at it, that perhaps those of us who fear that maybe we were moving a little too fast in drawing conclusions based on nonscience, that that is not necessarily true.

Ms. BROWNER. Well, first of all, Mr. Chairman, as you said, this is required in the Clean Air Act. It is a mandatory phaseout. We are in a public comment and review period right now, soliciting all of the best advice that we can get in terms of methylbromide, its use, its effect in terms of the ozone.

We moved forward with our proposal because we wanted to have the debate, the dialog, now, so we could collect the information. We didn't want to be in a situation of sort of springing this on people a year or two before the mandatory phaseout required by the Clean Air Act.

Also, we did talk and work closely with the Department of Agriculture in making this decision—that by informing the public of the Clean Air Act and what it says about methylbromide, that this would help to stimulate the alternatives development that may be possible.

And so we are fully aware of the concerns being raised, and that is why we reached out to the public to involve them and to the scientific community and the farming community.

Mr. STENHOLM. My concern about this—and this is one that we are going to be really trying to work into the legislation before this subcommittee—is that somebody made a determination that methylbromide was an ozone depleter. Therefore, it qualified under the Clean Air Act.

Now we are finding, just as we have in previous determinations, where somebody determined something may or may not be factual. It was not necessarily based on what we like to call sound science. Therefore, there are reasonable questions being raised now.

Under the Clean Air Act, do you have any flexibility regarding this?

Ms. BROWNER. As I understand under the provision in the Clean Air Act, it is a mandatory phaseout. The science that is available to us and the scientific community, we believe, there is consensus.

And now it may well be, as you suggest, that there are those in the scientific community that don't agree with that consensus. And, hopefully, that will be made available to us in the process.

But this is—and you are right to note—it is a mandatory phaseout in the Clean Air Act.

Mr. STENHOLM. That is one of the reasons why I am somewhat complimentary of the decision that you have brought to us regard-

ing the Delaney clause and allowing flexibility rather than mandating, picking a line, 1 million, 2 million, picking a number.

In all of your testimony today and in response to questions, you have indicated that much of this is not an exact science, that it is going to constantly change.

And just like the National Academy of Sciences study regarding children, you have been very correct in emphasizing over and over that it was the methodology that we are talking about—no conclusions as yet—but the methodology of finding the answer to the questions of what we are doing to our food supply affects children. That is a critical difference from what many keep talking about regarding that NAS study.

So as we proceed, I think it is going to be—and, again, I say this for the edification of what press may be here. This needs to be denoted, needs to be understood, that we are talking about some very complicated scientific judgments that have to be made. We on this subcommittee are certainly going to be very concerned and cognizant of the need of protection of public health.

But if we do not do it within the context of science, sound science, allowing some flexibility, we are going to dig ourselves into holes we can't possibly get out of. And this could be one right now that could have a terrific effect on exports of agricultural products; and the very production of agricultural products could, in fact, have the kind of effect that you have indicated in the subject we are talking about today, your support for maintaining at least some flexibility in it.

And if we have not given you flexibility, I think that perhaps the committees of jurisdiction ought to be looking at what they have wrought upon us, and we probably have voted to do without the kind of serious consideration that I have heard brought before us today.

Let me conclude by just saying, thank you again for the work that you have done. The fact that the three of you are here today indicates to me your serious concern as you have expressed both publicly and privately. This is a critical issue. It is one in which we have to come up with some solutions. I appreciate your dedication to that effect. I assure you this subcommittee will be working in that same endeavor.

And I think, of the suggestions that Mr. Smith made early on and then repeated a moment ago makes the most sense for how we proceed: Take the best ideas that you have brought to us, the best ideas that other bills contain and other concerns that have been brought to us and some as yet to get brought to us, attempt to put that together in a workable form, and then work cooperatively through the legislative process to bring a bill to the full House that we can deliver to the President of the United States.

We need to move fast in this area and, therefore, we will. So we are talking about a matter of days and weeks, not weeks and months, where we will be prepared for a markup. I know that you have indicated your willingness to work with our staffs, et cetera; and immediately upon the rap of the gavel, that will begin.

Thank you for being here.

This hearing is adjourned.

[Whereupon, at 12:45 p.m., the subcommittee was adjourned, to reconvene, subject to the call of the Chair.]

[Material submitted for inclusion in the record follows:]

Carol M. Browner  
Administrator, U.S. Environmental Protection Agency  
Testimony on Pesticide Use and Protection of the Food Supply  
before the U.S. House Agriculture Committee  
Subcommittee on Department Operations and Nutrition

Prepared for Delivery  
September 22, 1993

Good morning, Chairman Stenholm and other members of the Subcommittee. I'm pleased to appear before you today to present the Administration's views on pesticide use and protecting the food supply. I want to thank Chairman Stenholm, Mr. de la Garza, and Mr. Roberts for your leadership on these issues.

I want to acknowledge that food safety is not an easy issue. It's an emotional subject -- and it should be. The proposal we present today represents the efforts of a wide variety of people -- including many fine people from the agricultural community -- to harness our expertise and our urgent concern, our best science and our most passionate caring -- for the benefit of our children and all Americans.

The Environmental Protection Agency, the Department of Agriculture, and the Food and Drug Administration have been working with farmers, environmentalists, consumer groups, and state agencies. Today we are proud to present a program that will reduce the many health risks posed by pesticides and improve the safety of our food supply, especially for our children.

We believe today's proposal is a giant step forward, an opportunity to break the logjam of competing and vested interests to ensure a rigorous standard for food safety that all Americans can rely on.

The need for change is urgent. Nationwide, we use more than a billion pounds of pesticides each year. Of the 600 pesticides now in use, two-thirds have never been subjected to any health standard whatsoever. We cannot and we will not tolerate the status quo.

The solution is to make substantial changes in two laws. First, to assure a greater degree of safety in the food we eat, we must reform the Federal Food, Drug, and Cosmetic Act. But the risks of pesticide use extend far beyond the dinner table. We need to protect the farmers, farmworkers and homeowners who handle pesticides. We need to reduce the dangers of pesticide runoff into our groundwater. And we need to decrease the threat to the plants and animals with which we share our world. For these reasons, we must also reform the Federal Insecticide, Fungicide, and Rodenticide Act, or FIFRA.

Let me describe the major provisions of the proposal.

First, we propose to take special steps to protect children. We have already committed to implementing recommendations made by the National Academy of Sciences in June, in a report entitled "Pesticides in the Diet of Infants and Children." Today, we propose that the law be changed to require EPA to make a specific finding of safety for every pesticide used on every food, particularly those eaten in large quantities by infants and children. This will require us to account specifically for the unique diets and susceptibility of children.

The National Academy of Sciences also suggested we look at exposure to pesticides in lawn care chemicals, drinking water, and insecticides used in the home. We'll follow this recommendation as well.

I feel strongly that these steps are absolutely necessary to ensure a new level of protection for our children.

Second, we propose to establish a uniform health-based standard that applies to all pesticides, all foods, and all risks to human health. We propose to reduce pesticide residue levels in food to ensure "a reasonable certainty of no harm" to consumers. Again, this follows a recommendation of the National Academy of Sciences.

Third, we call for strict new deadlines to ensure that all pesticides comply with the new standard within seven years.

Within six months of enactment, EPA will identify all pesticides suspected of being high-risk.

Within three years, all high-risk pesticides that do not meet the health standard will be off the market.

Within seven years, all remaining pesticides that do not meet the strict health-based standard will be off the market.

These deadlines will put the burden squarely on industry to prove that pesticides are safe.

The fourth part of the Administration proposal is to make good on our June 25 pledge to encourage a dramatic reduction in pesticide use. Today, EPA and the Department of Agriculture are announcing that within one year we will develop specific goals

for reducing pesticide use by the end of the decade. We will include farmers, environmentalists, and other interested parties in establishing these goals and implementation plans.

We are also proposing that by the year 2000, 75 percent of America's farmland would be using Integrated Pest Management methods. We are confident that we can reduce pesticide use and pesticide risk without any decrease in the quality of our produce or the output of our farms.

Let me very briefly mention three other provisions of our proposal:

First, under current law, pesticide registrations are good in perpetuity. We propose that pesticide registrations be renewed every 15 years. This requirement will ensure that all pesticides conform to the latest scientific standards, and it will promote the development of safer alternatives.

Second, we would make the registration of these safer pesticides a top priority.

And third, we would prohibit the export of pesticides that had been banned in the U.S. because of health concerns.

Before closing I want to add a personal observation. I come from Florida where agriculture is a key industry. In carrying out my responsibilities at the Department of Environmental Regulation there, I worked closely with the farming community. It was my experience that farmers wanted to use fewer pesticides to protect public health. Farmers welcomed the opportunity to protect themselves and their own families from pesticide risks.

They were eager to use alternative methods of pest control that were safer for the community and the environment.

I also want to say that it's vitally important to me as a mother to have confidence about the food on our dinner table.

I'm proud to say that today's proposal offers a higher level of protection than any pesticide package ever presented by any Administration.

It's been a pleasure to work with Secretary Espy and Commissioner Kessler on this important matter.

Now the Administration looks forward to working with farmers, consumer advocates, and the Congress to achieve our shared goals -- to protect our health, and to safeguard the environment we'll pass on to future generations.

(Attachments follow:)

ADMINISTRATION PESTICIDE/FOOD SAFETY LEGISLATIVE REFORMS:  
EXECUTIVE SUMMARY OF TESTIMONY

Last June, the Administration announced its commitment to reducing pesticide use and promoting sustainable agriculture through the development of legislative, regulatory, and administrative initiatives. Today, we are pleased to have the opportunity to present the results of our efforts to date.

The Administration's initiatives are designed to maintain and enhance food safety for all Americans, to address recommendations of a 1993 National Academy of Sciences (NAS) report on ways to improve pesticide regulation to better assure that children are fully protected from pesticide risks, and to strengthen regulatory agencies' ability to make and enforce sound, timely, science-based decisions to protect public health and the environment.

The Administration's pesticide/food safety reform package includes changes to both the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The heart of the proposal is the establishment of a strong, health-based standard that would apply to all pesticide residues in food. Existing residue tolerances would have to be reviewed and brought into conformity with the new safety standard within fixed time frames. The proposals allow for a transition period under carefully prescribed conditions that will help avoid undue dislocations in agricultural production but still ensure an absolute deadline for all tolerances to meet the new standard.

The principles that guided our work in developing legislative and regulatory proposals included:

- o a firm commitment to reducing risks to people and the environment that may be associated with pesticides, and especially to providing greater assurance of protection for children, while ensuring the availability of cost-effective pest management techniques;
- o recognition of the need to work with American farmers to develop and implement improved means of pest control, to reduce use of high-risk pesticides and promote greater use of integrated pest management (IPM) techniques, including biological and cultural pest control systems and other sustainable agricultural practices;
- o implementation of regulatory reforms and incentives for the development of pesticides that will eliminate or reduce risks.

Building on the recommendations of the NAS report and the input we have received from representatives of all interests concerned about pesticide use and regulation, we have developed a comprehensive set of legislative reforms we believe will allow us



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to make real progress in enhancing public health and environmental protection. Consistent with the approach of the National Performance Review, these changes will make government work better, and establish a more credible pesticide regulatory system that is based on sound science and is capable of acting promptly to reduce pesticide risks whenever they are identified.

The major elements of our reforms are outlined briefly below. Our formal testimony provides more detail on how these provisions would work and the benefits we expect from their implementation. In addition, the testimony gives an update on our progress in addressing the NAS report recommendations and developing pesticide use reduction strategies.

#### FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA) PROPOSALS

##### o TOLERANCE SETTING

Tolerances for pesticide residues in all types of food would be based on a strong, health-based standard, defined as "a reasonable certainty of no harm" to consumers of the food. For carcinogens this standard represents an upper-bound risk of 1 in one million over a lifetime, calculated using conservative risk assessment methods.

The statute would mandate use of the best available science and information in decision-making. In the absence of reliable information that could refine residue level estimates or other assumptions used in risk assessment, however, conservative default assumptions would be required.

The statute would also specify criteria for the types of factors EPA should consider in assessing pesticide risks as part of the tolerance setting process, including, for example, risks to potentially sensitive subpopulations.

##### o SPECIAL PROVISIONS FOR INFANTS AND CHILDREN

Our proposals for tolerance setting are directly responsive to the NAS recommendations that EPA consider unique aspects of children's diets and other sources of pesticide exposure. EPA would be required to issue specific findings that a tolerance is safe for infants and children from potential pesticide risks.

EPA would also follow the NAS recommendations of looking at multiple exposures when establishing a tolerance and vigorously pursuing more accurate data on children's consumption habits. FDA would prioritize monitoring of residues on the foods children eat most.

o **REVIEW OF EXISTING TOLERANCES**

EPA would be required to review all existing tolerances and ensure that they meet the new standard within seven years of enactment.

Special fast track provisions would require priority review of pesticides which, based on currently available data, appear not to meet the safety standard. EPA would have to identify these pesticides within 180 days of enactment. The review of 75% of these tolerances will be complete within three years, and the review of all these tolerances will be completed no later than four years after enactment.

o **TIME-LIMITED TRANSITIONAL TOLERANCES**

EPA could grant time-limited transitional tolerances of no more than five years for a pesticide identified during the tolerance review process as not meeting the safety standard, if the loss of the pesticide would result in significant disruption in the food supply.

Under no circumstances would such time-limited tolerances be granted for pesticide risks that are an order of magnitude greater than negligible risk. The total time tolerances for such pesticides could remain in effect could not exceed 10 years after enactment. The burden would be on the tolerance sponsor to make the showing needed to support a time-limited tolerance, and to report biannually to EPA on efforts to reduce risks to negligible and the continuing existence of the effects that warranted the initial extension of the tolerance.

A greater than a time-limited tolerance extended under these provisions could only be renewed if Congress enacted a statutory exemption.

Both the tolerance review and transitional, time-limited tolerance provisions are responsive to NAS recommendations that tolerance setting be health-based, and that risk assessments incorporate improved toxicology and exposure data.

**IMPROVED REGULATORY COORDINATION AND NEW ENFORCEMENT TOOLS**

Both FIFRA and FFDCA should explicitly recognize and require that changes made to one statute should be reconciled with complimentary action under the other statute for issues relating to pesticide use on food. Additionally, FDA should have enhanced enforcement authorities to recall and embargo violative foods as well as to levy civil penalties, and have access to certain pesticide-related records.

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)  
PROPOSALS

o **REGISTRATION "SUNSET"**

Pesticide registrations and tolerances must be renewed every 15 years to ensure they are in conformity with health standards. This will apply unless a new application meeting current scientific standards is received by year 12 after registration and approved by EPA.

o **PHASE-OUT/PHASE-DOWN**

Whenever credible scientific evidence indicates that a pesticide is reasonably likely to pose a significant risk to humans or the environment, EPA could by rule-making take steps to limit the potential risk by requiring the phase-out or phase-down of the pesticide's use, for example by imposing production caps or eliminating uses. EPA would consult with USDA in establishing phase-out requirements.

o **STREAMLINING LABEL CHANGES AND ESTABLISHING A SINGLE, UNIFORM LABEL COMPLIANCE DATE ("LABEL CALL-IN")**

Modeled on the existing "data call-in" provisions of FIFRA Section 3(c)(2)(B), this authority would establish a streamlined process for achieving relatively small changes in the conditions of registration (e.g. label changes that reduce pesticide risks but do not affect the availability of a pesticide for use on any particular site).

An annual uniform labeling effective date would be established, and registrants would be able to make label changes in a predictable, orderly fashion.

o **INCENTIVES FOR DEVELOPMENT OF REDUCED RISK PESTICIDES**

EPA would establish criteria for designation of reduced risk pesticides. Registration applications that appear to meet the criteria would qualify for priority review, and, if approved, would be accorded two additional years of exclusive data use, beyond the ten years now provided in FIFRA.

Also, EPA would be authorized to grant special time-limited conditional registrations for biologically-based pesticides posing low potential risks.

o **PESTICIDE RISK AND USE REDUCTION AND SUPPORT FOR INTEGRATED PEST MANAGEMENT**

The Administration is calling for a joint EPA-USDA chaired effort to, within one year, develop commodity-specific pesticide use reduction goals.

The statute would state a clear policy goal favoring reduced use and direct federal agencies to take a leadership role in promoting use reduction and IPM in their programs.

The statute would authorize regional ecosystem-based reduced use pilot projects designed to reduce aggregate pesticide risks and set a goal for development of IPM programs and implementation strategies for 75% of acreage within 7 years of enactment. EPA and USDA would be mandated to work together to identify the research, education and extension activities that are most promising in terms of opportunities for reducing use of pesticides that raise risk concerns.

The current prohibition on requiring IPM training as part of certification and training programs would be repealed.

EPA would be authorized to establish criteria for "prescription use" of pesticides. Such authority could permit retention of pesticides critical to IPM and pesticide resistance management programs.

o **IMPROVED PESTICIDE DATA COLLECTION**

Following the model of the 1990 Farm Bill provisions, which require record keeping for restricted use pesticides, the Administration calls for record-keeping on all pesticide uses.

EPA and HHS will continue to pursue better incident monitoring and surveillance systems.

o **PESTICIDE MINOR USES**

Incentives for registering minor uses would include priority review and extended exclusive data use rights. In reregistration, unsupported minor uses lacking only residue chemistry data could continue until the last study for the pesticide is due, and registrants would have until that date to supply data for the minor use.

EPA, HHS/PHS, and USDA would collaborate to identify critical public health minor uses that might otherwise be lost, and to arrange for necessary data support, with HHS/PHS playing a role analogous to that of USDA in the IR-4 program for agricultural minor uses.

o **CANCELLATION, SUSPENSION, AND TOLERANCE REVOCATION PROCEDURES**

Cancellation and tolerance revocation procedures would be amended to replace formal, trial-type ALJ proceedings with a notice-and-comment cancellation process. Suspensions would be decoupled from cancellation procedures, and the time-consuming and cumbersome ALJ process for challenging

suspensions would be replaced by a petition procedure and prompt judicial review.

o **ENFORCEMENT AUTHORITIES**

Improvements in enforcement authorities would include enhanced inspection, record keeping and lab audit authorities; "whistle blower" and citizen suit provisions; and significant increases in penalties for FIFRA violations, commensurate with the nature of the offense. All regulations under FIFRA would be fully enforceable.

o **PREVENTING EXPORT OF PESTICIDES BANNED BY EPA**

Export of any pesticide to a country that has decided that it does not want to receive shipments under the terms of the international system of "Prior Informed Consent" (PIC) would be prohibited, as would export of any pesticide that has been denied registration or administratively or voluntarily canceled for all or virtually all uses in the U.S. based on health concerns or those pesticides that were voluntarily canceled in U.S. by the manufacturer for health or safety reasons. Never-registered food use pesticides could only be exported if there were a U.S. tolerance for the active ingredient and/or a method capable of detecting residues in food.

o **FEES TO SUPPORT FIFRA '88 REREGISTRATION**

The proposal would include authority to impose a new one-time supplemental reregistration fee assessed on an active ingredient basis and an individual product reregistration fee. Annual maintenance fees as required under the current reregistration program would continue.

TESTIMONY OF  
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BEFORE  
SUBCOMMITTEE ON DEPARTMENT OPERATIONS AND NUTRITION  
COMMITTEE ON AGRICULTURE  
U.S. HOUSE OF REPRESENTATIVES

SEPTEMBER 22, 1993

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## I. INTRODUCTION

Good morning Chairman Stenholm and Subcommittee members. We are pleased to appear before you today to present the Administration's views on important issues relating to food safety, pesticide use, and pesticide regulation.

In late June, the Administration announced its commitment to reducing the use of pesticides and promoting sustainable agriculture in this country. We stated our intention to work to reduce risks associated with pesticides for all Americans, and especially, to ensure appropriate protection for children. We also pledged to intensify our efforts to facilitate the availability of alternative and effective pest management tools.

Since that announcement, the Environmental Protection Agency (EPA), the U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA) have been meeting together and with a number of interested parties, including: farmers, environmentalists, consumer groups, state agencies, industry, and others, to discuss the measures that need to be taken to achieve the goals that we set forth in June. We have developed a three part program involving both legislative and administrative initiatives.

First, we want to strengthen existing statutory authorities governing pesticides. Second, we pledge to upgrade the science related to pesticides and food safety, especially as it applies to the protection of children. We are addressing the recommendations put forth in the 1993 National Academy of Sciences (NAS) report, "Pesticides in the Diets of Infants and

Children." Third, we are reorienting our efforts to focus on preventing problems at the source, through appropriate reduction of pesticide use. History teaches us that in all aspects of life, prevention saves time, energy, and resources. By stressing prevention, we not only safeguard today's children, we look beyond to protect the health and environment of future generations.

## II. PESTICIDE/FOOD SAFETY LEGISLATIVE REFORMS

Soon after the inauguration, the Administration began focusing on pesticide matters. Earlier this year, key members of Congress turned to the Administration for leadership in resolving the very complex administrative and legislative issues posed by current agricultural, public health, and environmental laws and policies. Under the auspices of the White House Domestic Policy Council, representatives of EPA, USDA, the Department of Health and Human Services (HHS) and its FDA have worked closely together over the last seven months to develop a comprehensive set of reforms that can provide a new direction and depolarize much of the debate about pesticide and food safety legislation that has too long prevented enactment of meaningful legislative change in this area. The progress we have made is significant, and we are pleased to have the opportunity to present our views to you today.

It is important to acknowledge at the outset that the issues we will be discussing today, and that have been debated in the halls of Congress and elsewhere for several years, are

exceedingly difficult and complex. Many stake holders are involved: individual citizens concerned about the potential effects of pesticide use on their health and the environment; the public health, environmental and consumer communities; the agricultural production, pesticide manufacture, and food processing and distribution industries; scientists; and officials at all levels of government who are charged with developing and implementing our pesticide and food safety laws. The scientific and technical considerations are complicated and evolving, and require dealing with uncertainties. This is why it has been so difficult in the past to achieve broad consensus on the reforms that will best reflect sound science and our common goals of environmental and public health protection within a growing economy.

Our proposals require amendment of both major pesticide regulatory laws: the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Only by reforming both statutes can we achieve our food safety, health and environmental protection goals and establish a consistent framework for timely regulatory decision-making.

Clearly, we will need to work closely with all four Congressional committees who have jurisdiction over these statutes in order to ensure passage of sound legislation. Interagency deliberations are ongoing, and we welcome the opportunity to work with you, our sister regulatory agencies in

the states, and others in the public health, environmental, consumer, agricultural, and food marketing and processing communities to refine our proposals in the coming weeks and months.

#### FEDERAL FOOD, DRUG, AND COSMETIC ACT (FFDCA) PROPOSALS

The Administration's key proposals for amendments to the FFDCA are central to our goal of maintaining and enhancing the safety of our food supply from pesticide risks, with particular emphasis on ensuring that our children are protected. We will achieve these objectives by: (1) establishing a strong, protective and health-based safety standard for pesticide residues in all types of food; (2) providing for a timely review of all existing tolerances to ensure they meet that standard; and (3) strengthening the authorities of our food safety regulatory agencies to carry out their responsibilities under the law.

#### TOLERANCE SETTING

The standards for tolerance setting under the FFDCA need to be reformed and updated in order to allow EPA to use the best, state-of-the-art science in establishing and reassessing tolerances for pesticide residues in food that will fully protect public health. This can best be achieved by amending the law to require EPA to set tolerances based on a strong, health-based safety standard of reasonable certainty of no harm to consumers of food. Specifically for carcinogens, this would mean that the dietary risk is negligible. This standard is consistent with the standard generally applied to food additives.

As recommended in the 1987 NAS report, "Regulating Pesticides in Food: The Delaney Paradox," this new standard would replace the conflicting standards that now apply to pesticides found in raw and processed food, including the Delaney clause which governs certain residues of pesticides that concentrate in processed food or are added in food processing.

Legislation currently before Congress further demonstrates the consensus that replacing current law, including the Delaney clause, with a health-based safety standard would greatly benefit the public health.

The reasonable certainty of no harm/negligible risk standard represents an upper bound risk of one in one million ( $10^{-6}$ ) over a lifetime, calculated using conservative risk assessment methods. For carcinogens, EPA would use this approach to implement the negligible risk standard that the Administration is proposing. In evaluating threshold effects, defined as effects that are not expected to occur below certain exposure levels, the agency would use the equivalent of a 100-fold uncertainty or "safety" factor, applied to the No Observed Effect Level (NOEL) derived from animal studies, unless the available data supported using a different factor for a particular chemical or until improved methods of quantifying threshold risks are developed. Any future modifications in EPA's implementation of the safety standard would have to be based on sound science and provide assurance of

the same, or greater, level of protection as these current approaches.

The Agency should have a mandate to use the best available information in its decision-making. However, in the absence of reliable information that could refine residue level estimates or other assumptions used in risk assessment, the law should require EPA to make conservative default assumptions. EPA would assume high food consumption rates that residues are present at tolerance levels and 100% of the crop is treated. Thus, in the absence of adequate data and information, the Agency would make protective assumptions that would tend to overstate potential risks. Nonetheless, in order to ensure that future EPA decisions and risk assessments will reflect the best of evolving science, the statute itself should not prescribe in detail the risk assessment assumptions and methodology that the Agency should use in evaluating whether a pesticide meets the safety standard.

The statute should also specify criteria for the types of considerations EPA should take into account in assessing pesticide risks as part of the tolerance setting process. For example, EPA should consider other potential routes of exposure to the same or related chemicals, through drinking water or non-dietary exposures, risks of other chemicals causing the same effect(s) and risk to potentially sensitive subpopulations. Where appropriate, EPA should also consider food distribution patterns in assessing potential exposure.

**SETTING TOLERANCES FOR INFANTS AND CHILDREN**

The Administration is absolutely committed to maintaining and enhancing food safety for infants and children. Our proposals for tolerance setting are directly responsive to recommendations in the NAS report on "Pesticides in the Diets of Infants and Children" that EPA consider unique aspects of children's diets and nondietary sources of pesticide exposure. They would also ensure implementation of NAS recommendations that tolerances be based on health considerations and that risk assessments incorporate use of improved toxicology and exposure data, consistent with evolving science.

To ensure that children receive appropriate attention, we would support provisions that require EPA, when establishing a tolerance to publish the specific finding that the tolerance is protective for children from potential risks and the basis for that finding. As acknowledged by the NAS study, full information on consumption habits for infants and children is not up-to-date. However, we do not believe implementation of this provision would need to be delayed pending development of new data. We support additional funding for USDA to collect improved food consumption data for children and that the foods that children eat be a top priority in residue monitoring. To the extent possible, we will also look at food consumption across the range of the population and not just for the average child. In the absence of data on children's consumption patterns, the EPA will employ conservative

estimates which will be used unless the registrant can provide more accurate data.

In establishing tolerances, the statute should also direct EPA to look at the multiple sources of exposure to a pesticide - a recommendation that the NAS believes will be especially beneficial to infants and children. For example, EPA would look at exposure to a pesticide on lawns, in homes, in drinking water, and in other foods, and evaluate these risks when setting a new food tolerance. The EPA will also look at exposures to multiple pesticides that cause the same health effect. Although the science is new and emerging in how to look at multiple exposures, EPA will develop new methodologies through its research programs and will apply these whenever possible.

Finally, we are committed to improving the openness and accessibility of our regulatory decision-making. The bases for all our tolerance decisions should be clearly documented and open to public scrutiny. If EPA, on the basis of sound information and data, refines the assumptions made in risk assessments to more closely approximate actual exposure, rather than assuming that 100% of the food contains residues at the tolerance level, that should be clearly laid out for public notice and comment as part of the tolerance decision. We would also support provisions requiring EPA to reexamine such tolerances periodically, to ensure that the refined assumptions remain valid, and providing authority for the agency to require tolerance sponsors to generate additional data when needed as part of the re-

examination or to assure EPA that the major factors impacting exposure (and therefore risk) are still valid. We would like to discuss with Congress the exploration of provisions such as the requirement to develop additional data on actual residue levels and the establishment of separate tolerances for food beyond the farmgate to ensure that legal food is safe food. The Keystone food safety policy dialogue could provide a useful starting point for the exploration of these provisions.

**TIMELY REVIEW AND ACTION ON EXISTING TOLERANCES TO ENSURE COMPLIANCE WITH THE NEW SAFETY STANDARD**

One of the highlights of our proposal is a fundamental change in the approach to regulating the safety of pesticides in the food supply: a self-executing statutory requirement that forces all tolerances to meet the new safety standard by fixed deadlines. The Administration proposes that the review of all tolerances be completed within seven years after enactment of a legislative reform package, and that pesticide tolerances that now appear not to satisfy the safety standard be subject to special "fast track" review procedures.

Under our proposal, EPA would be required to complete review of all existing tolerances to ensure that they meet the safety standard within seven years of enactment. The burden is on the tolerance sponsor to show that the statutory standard is met. If the Agency determines that this burden has not been met, the tolerances would expire and complementary FIFRA cancellations would be triggered without further analysis or proceedings.

In some cases, a "pipeline" period may be permitted for legally treated food to clear the channels of commerce or for unavoidably persistent residues to dissipate. EPA's determinations would be judicially reviewable if challenged within 60 days, but the revocations and cancellations would take effect unless a court orders otherwise.

If EPA failed to complete the tolerance reviews within the seven-year time frame, the Administrator would have the authority to extend tolerances for up to one additional year to allow completion of review and a determination by the Agency whether the standards are met. This extension could only be granted if the Administrator makes a finding that tolerance sponsors have fulfilled their commitment to supply the information required for agency review in a timely fashion and that the extension would not adversely affect public health.

In summary, this approach ensures re-evaluation of all tolerances within seven years. For pesticides subject to reregistration under amendments to FIFRA enacted in 1988 (FIFRA '88), we expect tolerance review will track reregistration schedules. For newer tolerances established since 1984, EPA will have to develop a schedule to complete review within the seven-year period.

SPECIAL 'FAST TRACK' REVIEW. Special expedited review provisions would apply to pesticides which, based on information available at the time of enactment, appear not to satisfy the safety standard. Within 180 days of enactment, EPA would

identify such potentially higher risk pesticides for priority attention. The review of at least 75% of these tolerances should and will be complete within three years, and all will be completed no later than four years after enactment.

Of course, independent of these new tolerance review and "fast track" provisions and the time-limited transitional tolerance proposal outlined below, EPA would be able to act at any time to revoke or modify tolerances using standard procedures or to parallel action taken to suspend or cancel registrations under FIFRA.

#### TIME-LIMITED TRANSITIONAL TOLERANCES

Under the reforms we propose, EPA would establish tolerances for new pesticides uses only if they meet the new safety standard.

In the tolerance review, however, we would propose to give EPA the authority to maintain tolerances for a non-renewable period of no more than five years for a chemical that does not satisfy the standard if justified to maintain direct health benefits to consumers or to avoid significant disruption in the food supply.

Under no circumstances would such time-limited tolerances be maintained for pesticide risks that are an order of magnitude greater than negligible risk. Tolerances for such pesticides could remain in effect for at most 10 years after enactment. The burden would be on the tolerance sponsor to make the showing needed to support a time-limited tolerance, and to report

biannually to EPA on efforts to reduce risks to a negligible level and the continuing existence of the circumstances that warranted the initial extension of the tolerance.

If at any time during the period of any time-limited or transitional tolerances the Agency concludes that circumstances no longer justify maintaining the tolerance, EPA would revoke the tolerances before the expiration date. An example would be if a safer alternative pest control method were developed for the affected uses so that loss of the pesticide would no longer result in a significant disruption of the food supply beyond ordinary fluctuations. FIFRA product registrations would be automatically canceled upon the expiration or revocation of the corresponding tolerances.

Tolerances still not meeting the safety standard at the end of any tolerance extension period could only be renewed if Congress enacted a statutory exemption.

The proposed tolerance review strategies are responsive to NAS recommendations that tolerances be based on health considerations, and that risk assessments incorporate use of improved toxicology and exposure data. It will ensure that all tolerances meet the new health-based statutory standard within fixed time-frames, unless Congress intervenes.

#### PROVIDING REGULATORY AGENCIES WITH IMPROVED ENFORCEMENT AND OTHER TOOLS

In addition to strong new standards for tolerance setting and the tolerance review program, we are proposing additional

authorities to improve our agencies' ability to carry out their regulatory responsibilities. For example, we would support a provision in FFDCA analogous to the provision in Section 3(c)(2)(B) of FIFRA that would authorize EPA to require new studies whenever needed to support an existing tolerance, including studies on improved testing procedures and actual residue monitoring data when appropriate. This concept is included in the bills sponsored by Chairmen Kennedy and Waxman. While in most instances EPA can use the "data call-in" authority of FIFRA to require such information, a parallel FFDCA provision could be useful in cases where a pesticide has U.S. tolerances under FFDCA but no U.S. registration under FIFRA.

Similarly, FDA should have enhanced enforcement authorities to recall and embargo violative foods as well as to levy civil penalties.

#### IMPROVING COORDINATION BETWEEN FIFRA AND FFDCA

Both FIFRA and FFDCA should explicitly recognize and require that actions taken pursuant to one statute should be reconciled with a complementary action under the other statute for issues relating to pesticide use on food. For example, when a tolerance is modified or revoked under FFDCA, FIFRA should require a conforming action relating to use. FFDCA should also have a sunset provision which conforms with the FIFRA sunset proposal. In addition, FFDCA tolerance revocation procedures need to be streamlined in a similar manner as FIFRA suspension and cancellation procedures.

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)PROPOSALS

The focus of FFDCA reform is on food safety and potential dietary risks. Our proposals for reforming FIFRA would complement FFDCA initiatives and expand on them to enhance our ability to improve pesticide regulation and use across-the-board. The two sets of proposals form a balanced package and in our view are inextricably linked. We must have a consistent, comprehensive scheme for addressing all pesticide risks.

The major goals of our FIFRA reforms are to better enable us to reduce or eliminate potential pesticide risks to health or the environment, to strengthen our efforts to reduce pesticide use, to encourage development of safer alternatives, and to provide a broader range of regulatory and enforcement authorities to improve compliance with pesticide regulations. The Administration's proposals would not only improve food safety, they would also enhance our ability to deal with farm worker risks, groundwater contamination, hazards to endangered species, and exposures of children and others to pesticides used for lawn care or residential pest control, or that may in any way affect our daily lives and our environment.

**REGISTRATION "SUNSET"**

Our policy goal in proposing a "sunset" for pesticide registrations is to ensure that all pesticides are reviewed periodically and are taken off the market if the data supporting their continued registration do not meet up-to-date scientific standards for safety testing.

Currently, pesticide registrations generally have no fixed expiration or renewal dates. Even the massive reregistration program EPA is currently implementing under FIFRA '88, covering all pesticides first registered before November 1984, does not involve any automatic "sunset" or sanction against pesticides that are found ineligible for reregistration. We propose to amend FIFRA to provide for a sunset for all pesticide registrations. Future registrations would expire in 15 years unless a new application meeting the then-current scientific standards is received and approved by EPA.

For existing pesticide registrations subject to FIFRA '88, the 15-year period would begin on the date EPA issues a reregistration eligibility decision, or "RED"; for new pesticides, it would generally begin on the date of initial registration. Applications for renewed registration would be due to EPA in the twelfth year of the 15-year period, to allow time for agency review of the new data submitted.

In order to maximize efficiency, we are considering setting sunset dates on an active ingredient basis. The sunset date for an active ingredient would apply to all products containing that

active ingredient. As a practical matter, this would mean that individual product registrations could have varying terms. For example, if a new producer registers a product containing active ingredient A in 2010, and active ingredient A was initially registered in 2000, the new product's registration would only be good through the 2015 expiration date for the active ingredient. It could be renewed only if an application for renewed registration of the active ingredient were submitted by 2012 and approved by EPA before the expiration date.

This approach will place the burden on registrants to identify and supply all the data needed to keep their registrations up to date with current EPA standards. If they do not submit a new application by year 12, or if the application is deficient, the registrations will simply expire in year 15, without additional time for data development or the need for EPA to initiate cancellation proceedings. Like the FIFRA '88 reregistration program, EPA will need authority to charge fees to help cover the costs of reviewing renewal applications.

Like our proposal for tolerance review, if registrants submit complete, timely applications but EPA does not complete its review and issue a registration renewal decision by year 15, the Agency would have the authority to extend the registration for an additional year, contingent on a finding that the registrant had submitted a complete and technically adequate application on time. Also, at any time before the sunset date,

EPA could initiate action to cancel or suspend the registration, or to require additional data under FIFRA Section 3(c)(2)(B).

#### **PHASE-OUT/PHASE-DOWN**

Under current FIFRA, full pesticide production and use often continue for years while data are generated to resolve scientific questions, and the public bears the potential risk. Our new phase-out/phase-down proposal would give EPA an important new regulatory tool to begin to reduce potential pesticide risks when new questions arise about safety of registered products.

Whenever credible scientific evidence indicates that a pesticide is reasonably likely to pose a significant risk to humans or the environment, EPA could, by rule-making, take steps to limit the potential risk by requiring the phase-out or phase-down of the pesticide's use, for example, by imposing declining production caps or elimination of uses. EPA would consult with USDA in establishing phase-out strategies to avoid unnecessary dislocations in agricultural production.

The phase-out could be complete over time (e.g., production caps down to zero production by year 5 of a five year phase-out rule), or less than complete. If, during the phase-out process, the risk concerns are resolved, phase-out controls would be removed. Alternatively, at any point during the phase-out, if the data support a cancellation or suspension finding, EPA could invoke those procedures.

Both the public and agricultural producers will be served by this tool. Phase-out authority is an intermediate sanction that

can provide time for gradual readjustment of pesticide users and for the development of alternatives, easing the transition for users as compared to total cancellation. Moreover, it allows EPA to act to reduce potential risks while scientific uncertainties are being resolved. We also believe it would increase incentives for prompt data development and voluntary interim risk reduction measures early in the process, once new risks were identified.

#### IMPROVING PESTICIDE LABELS, STREAMLINING LABEL CHANGES, AND ESTABLISHING A SINGLE, UNIFORM LABEL COMPLIANCE DATE

Significant protection of public health and the environment can be made through changes to pesticide labeling. The Administration's proposals would dramatically speed and simplify the process for making changes which in turn could substantially improve protection for farm workers, homeowners, wildlife, and ecosystems. Currently, EPA lacks a streamlined mechanism to require minor labeling, packaging, or formulation changes and may have to resort to cancellation procedures. EPA has also often been criticized for a lack of uniformity in pesticide labeling. Our proposal would streamline procedures, improve consistency and establish a single annual compliance date for most required changes.

Full cancellation procedures are a wasteful and inappropriate way of achieving relatively small changes in the conditions of registration (i.e., label changes that reduce pesticide risks but do not affect the availability of a pesticide

for use on any particular type of crop or site). We expect many such changes to flow from FIFRA '88 reregistration decisions, and registrants may not always agree to make the changes voluntarily. A streamlined mechanism for implementing label changes would help ensure that the benefits of reregistration are realized without undue delay. Examples of the types of changes that could be made through the streamlined process include requirements for protective clothing and equipment, limitations on applications to protect endangered species or groundwater, increases in pre-harvest or worker re-entry intervals, and additional warning statements. Changes that would essentially eliminate the use of the pesticide on any use site could not be implemented through the new process, but would remain subject to cancellation procedures.

Coupled with the streamlined process would be the establishment of a single, uniform effective date each year for all EPA-required labeling changes, except in instances where the agency believes the change is too urgent to delay. This will give registrants ample notice and time to arrange for new labels to be printed in an orderly, predictable fashion.

The process we envision for this streamlined "label call-in" provision would be modeled on EPA's existing data call-in authority in Section 3(c)(2)(B) of FIFRA. Once EPA has determined that a change is necessary, the Agency would notify affected registrants of the new requirement and explain the basis for the agency's determination. Registrants would have 60 days

to object to the requirement. The basis for objection could be the registrant's contention that the change essentially eliminates an entire use site and thus requires full cancellation procedures. Alternatively, the registrant could present data and information demonstrating that the change is not necessary or appropriate for the particular product or that another change would be equally or more effective in addressing EPA's concerns.

EPA would then have 90 days to respond to the registrant's submission and state its reasons for continuing, modifying or withdrawing the proposed requirement in light of the arguments made by the registrant. EPA's decision would be judicially reviewable if challenged within 60 days. The basis for review would be the record of written exchanges between the agency and the registrant.

Unless ordered otherwise by a court (or EPA determines that urgency requires more expeditious action to address significant risk concerns), changes will take effect on the next applicable uniform effective date. (At present, we are considering setting effective dates that would provide no less than 12 months notice before the change would be required in the normal course of events.) Failure to make changes would result in suspension, and products without updated labels that enter commerce after the relevant effective date would be subject to seizure or mandatory recall, and other appropriate enforcement action.

Following the data call-in authority model, the only grounds for challenging enforcement action would be a factual dispute as

to whether the required change was made. We would expect judicial review of EPA's final decision to be completed and the issue resolved in time for registrants to meet the uniform compliance effective date.

#### **INCENTIVES FOR DEVELOPMENT OF REDUCED RISK PESTICIDES**

The Administration is committed to reducing pesticide risks and encouraging the development of safer alternative means of pest control, including nonchemical control alternatives. As an adjunct to our ambitious administrative initiatives, a legislative reform package should include provisions to give greater priority to these efforts in both EPA and USDA programs. Just as we need to take expeditious action to remove from the market products that pose unacceptable risks, we must also speed the development and approval of safer substitutes so that pesticide users will have access to the pest control alternatives they need.

Our proposal would direct EPA to establish criteria for designation of reduced risk pesticides. Registration applications that appear to meet the criteria will qualify for priority review, as described further below. Once approved, pesticides meeting the criteria will be accorded two additional years of exclusive data use, beyond the ten years provided in current FIFRA. EPA would also be authorized to grant time-limited conditional registrations for biologically-based pesticides, if, before a full data set is developed, the Agency determines that the pesticide is unlikely to pose a risk of

unreasonable adverse effects on health or the environment during the period required for full data development and review.

EPA's registration program review priorities would be set as follows:

- (1) Registration of products that would eliminate future FIFRA Section 18 emergency exemption applications;
- (2) Pesticides that reduce risk compared to currently registered alternatives (e.g., by replacing a pesticide subject to phase-out or cancellation proceedings or that has been identified as posing greater than negligible dietary risk);
- (3) Pesticides that meet EPA criteria for designation as "reduced risk";
- (4) Minor use registration applications;
- (5) Other applications.

## PESTICIDE RISK AND USE REDUCTION AND SUPPORT FOR INTEGRATED PEST MANAGEMENT

As announced on June 25, 1993, promoting pesticide use reduction for pesticides that raise risk concerns, is a major goal of this Administration and is reflected in our legislative reform proposals. Today, EPA and USDA are announcing the beginning of a one year process to develop specific pesticide use reduction goals for various segments of production agriculture to be achieved by the year 2000. EPA and USDA will jointly chair this effort which will include farmers, environmentalists, and other interested parties. We envision that this effort will build on and significantly expand ongoing projects looking at commodity clusters. For example, EPA has initiated an intense review of insecticides used on corn. The objective of this project is to vigorously pursue pesticide use and risk reduction while providing necessary crop protection.

In 1992, a broadly representative group of growers and environmentalists called for a national commitment to promote Integrated Pest Management (IPM). We are setting a goal of developing and implementing IPM programs for 75% of total crop acreage within the next 7 years. We believe Congress should endorse that goal.

Increased use of is firmly grounded in an environmental ethic of pollution prevention, a keystone of Administration policy in all sectors, including agriculture.

The statute should set a goal for USDA, in consultation with EPA, to develop IPM strategies that would cover a certain percentage of total crop acreage by a fixed date. We also believe the statute should direct federal agencies to take a leadership role and to adopt in their own pest management activities the same risk reduction and IPM approaches that private interests are being encouraged to adopt. EPA, USDA, and the Fish and Wildlife Service, should also be directed to institute a process for coordinating environmental risk reduction efforts with research efforts, through identification of pesticides that raise risk concerns and for which development of use direction programs and research on safer alternative means of pest control should be high priority for USDA research programs.

Recognizing the need to implement in the field our commitment to reduce pesticide use, we support a provision authorizing the establishment of several pilot ecosystem-based reduced use programs, tailored to specific regions and involving all stakeholders (growers, homeowners, government officials, industry and others). These programs should focus on reducing aggregate pesticide risks.

We also support the use of market-based incentives to help achieve environmental progress, and we will explore additional options to bring these incentives to bear as part of our use reduction initiatives. This might include use of food label claims to encourage purchase of food with reduced use of pesticides.

Two other legislative changes would further our use reduction initiatives. First, FIFRA's current prohibition on requiring IPM training as part of certification and training programs should be repealed. Second, to ensure that adequate tools are available to carry out IPM programs, some pesticides should remain available for use under selective and controlled circumstances. Thus, EPA should have the authority to establish criteria for "prescription use" of pesticides. Such authority could permit retention of pesticides critical to IPM and resistance management programs or otherwise to reduce pesticide risks, and could be modeled on the state management plan approach EPA is currently implementing for groundwater protection. Under this approach, EPA would limit registration of certain pesticides to states which have developed appropriate management plans aimed at ensuring that they are only used in appropriate circumstances, upon "prescription" of qualified pest control advisors.

#### EXPANDED PESTICIDE USE DATA COLLECTION

Sound pesticide regulation depends on high quality data and information to support decision-making. The changes in the regulatory system we are proposing will create greater incentives for the timely submission of data from registrants. By the same token, we must also ensure that information collected and used by government agencies is current, complete and reliable.

We propose the following measures to help ensure that data collected and generated by the federal government is

comprehensive and valid for use in making decisions about pesticides and their impacts.

- o In keeping with the recommendations of the NAS, we plan to enlarge and improve the data base on foods consumed by infants and children. We look forward to working with Congress to find the funding to increase USDA's survey efforts in compiling consumption data, especially for children. This information will help us to fulfill our objective of increasing our assurance that children are protected from pesticide risks.
- o The availability of accurate pesticide use information can help refine "default" assumptions and enable EPA to make more realistic exposure estimates in setting tolerances. USDA proposes to expand the scope and detail of its pesticide use surveys to include more crops and more states and, in addition, to conduct a national baseline survey of all pesticide use on a periodic basis. Given the importance of reliable information in making percent-of-crop-treated assessments, we also propose to expand current record-keeping requirements to include all pesticides used in agricultural production. While protecting confidentiality, following the model of the 1990 Farm Bill, this new record-keeping authority will help ensure the reliability of information used in decision-making. It can also be important in diagnosing and following up on problems and

developing targeted risk mitigation strategies for vulnerable areas.

In addition, we want to enlist the support of health professionals and others in identifying risks to health and the environment, particularly with respect to worker exposures. The Administration expressed its commitment to better incident monitoring earlier this year, and EPA has already undertaken efforts to strengthen programs in this area. We want to explore additional avenues for making our systems more useful and effective.

The Administration is also looking into the role of HHS research and surveillance programs related to the health effects of pesticides on farm workers. EPA and HHS need to work closely together to identify and collaborate on the highest priority research needs. Current HHS surveillance activities are focused on the collection, analysis and field investigation of reports of pesticide-related illnesses and injuries. HHS is working with three states testing various approaches, including physician, laboratory, and migrant clinic reporting. Better surveillance data, follow-up, and analysis should help identify pesticides posing the greatest risks to workers. This kind of information is useful in targeting pesticides for further review. It could help guide risk reduction efforts, and be directly relevant to regulatory decisions, for example, with respect to evaluating application rates and methods, the adequacy of personal protective equipment, and worker re-entry intervals.

## PESTICIDE MINOR USES

Generally, pesticide minor uses are considered to be those agricultural or public health uses for which anticipated sales revenues do not justify the expense of registering or reregistering a pesticide product.

The Administration supports the creation of incentives for registration of new pesticides for minor uses by giving applications that include three or more minor uses priority for review and extending exclusive data use rights for two additional years under FIFRA.

Existing minor uses are also at risk for lack of support in reregistration. The best solution to this problem is to ensure that the data needed for reregistration are developed, so that EPA can make timely decisions on these uses as well as on major uses on the basis of sound science and an adequate data base. For this reason, the Administration supports continued funding of USDA's cooperative IR-4 program, which has undertaken support of many residue field trial studies needed to support minor agricultural uses. In addition, we would support legislation to give minor uses the maximum time for development of residue chemistry data required under the FIFRA '88 reregistration program (until the last study due date for the chemical) and allow full time for data development when a minor use waiver request is denied by EPA.

Even with these proposals, some minor uses may be lost. Therefore, we would support legislative changes designed to ease

growers' transition to alternatives, by allowing minor crop uses to continue until the due date of the final study required in the reregistration process. This extension would only be permitted if no risk concerns have been raised, other uses of the pesticide are being supported, and only residue chemistry data related to the minor use are lacking support.

Finally, we recognize that some public health uses of pesticides may lack adequate economic incentives for registration and reregistration. We support legislation providing for the Department of Health and Human Services/Public Health Service and EPA to collaborate in identifying critical public health minor uses that might otherwise be lost, and to arrange for necessary data support, with HHS/PHS playing a role analogous to that of USDA in the IR-4 program for agricultural minor uses.

#### **CANCELLATION AND SUSPENSION PROCEDURES**

Cancellation procedures under FIFRA should be improved through the adoption of a notice-and-comment type cancellation process, to replace adjudicatory hearings before an Administrative Law Judge (ALJ). Final cancellation orders could be challenged in court, but the pesticide would be off the market unless the court overturned the cancellation.

Trial-type formal ALJ procedures as required under existing law are not the best way to resolve scientific issues. They are cumbersome and extremely time and resource-intensive for all parties. This change, combined with the other regulatory tools outlined above, will enable EPA to implement the benefits of

reregistration review more effectively and expeditiously. In addition, a notice and comment procedure will be more open to public participation and will be more accessible to all interested groups, such as agricultural producers who may have an interest in the issue but not be prepared to participate in a formal hearing.

While we are not advocating a change in the standards for suspension under FIFRA, we would propose that EPA's authority to issue suspensions in cases of "imminent hazard" be decoupled from cancellation procedures. Under current law, suspension orders must be issued at the same time as, or be preceded by, a proposed cancellation. We believe EPA should be able to issue the suspension in the absence of a proposed cancellation, provided that the cancellation proposal is issued within six months of the suspension. Failure to issue the proposed cancellation within the six-month period would result in automatic termination of the suspension.

We would also replace the time-consuming and cumbersome ALJ process with a petition procedure for challenging suspensions, with prompt judicial review. Petitions could be filed within 30 days by anyone who would be adversely affected by the suspension, and EPA would have to respond within 120 days. If EPA failed to respond within that time period, the suspension would be invalidated automatically. Any petitioner who is dissatisfied with EPA's response could seek judicial review. Alternatively, adversely affected persons could go directly to court for review

of the suspension within 10 days, bypassing the petition procedure. We believe these expedited procedures are appropriate when EPA has determined that an imminent hazard exists.

Consistent with these changes, FIFRA's judicial review provisions would be streamlined, consolidated, and clarified to eliminate the current confusion regarding how judicial review may be sought.

#### **ENFORCEMENT AUTHORITIES AND PREVENTING THE EXPORT OF PESTICIDES BANNED BY EPA**

Any legislative reform package must include major improvements in enforcement authorities and a strengthened penalty structure under FIFRA. Among the key provisions should be improved inspection and lab audit authorities and significant increases in civil and criminal penalties for FIFRA violations, commensurate with the nature of the offense. All regulations promulgated under FIFRA should be fully enforceable. For first time violations by farmers or other private applicators, the agency may exercise its enforcement discretion to issue warning letters, unless there is a knowing violation.

The Administration supports "whistle blower" provisions to help ensure that employees who report potential violations do not suffer recriminations from their employers. In addition, compliance with our pesticide laws and regulations would be enhanced by inclusion of a carefully-crafted provision for citizen suits under FIFRA and possibly under FFDCA, with prior

notice to responsible regulatory authorities at the state and/or federal level.

We would also propose to expand EPA's record-keeping authorities under FIFRA with respect to commercial applicators, pesticide dealers and laboratories that conduct testing to support pesticide registrations.

Finally, we support FIFRA amendments to make enforceable under U.S. law prohibitions on the export of certain pesticides. The Administration proposes enactment of several legislative changes in this area.

First, FIFRA should prohibit the export of any pesticide to a country that has decided that it does not want to receive shipments under the terms of the international system of "Prior Informed Consent" (PIC) established under the auspices of the UN Food and Agriculture Organization and the UN Environment Programme. The PIC system is designed to cover pesticides that have been prohibited for all or nearly all uses by participating countries, based on human health or environmental risk concerns.

Second, FIFRA should prohibit export of any pesticide that has been canceled for all or virtually all uses in the U.S. based on health concerns or those pesticides that were voluntarily canceled in the U.S. by the manufacturer for health or safety reasons. Approximately 50 pesticides would fall in this category, including pesticides that have been voluntarily canceled due to risk concerns.

Third, never-registered food use pesticides should only be allowed to be exported if there is a U.S. tolerance for the active ingredient and/or if there is a method determined by EPA to be capable of detecting residues in food.

#### **FEES TO SUPPORT FIFRA '88 REREGISTRATION**

Timely completion of EPA's FIFRA '88 reregistration review program is a critical component of all our efforts to make certain that pesticide risks are fully assessed and appropriate regulatory action taken. It is now clear that additional resources will be required for this program. An immediate \$20 million shortfall has been projected through the end of 1997.

To meet these program needs, the Administration supports enactment of a one-time supplemental reregistration fee assessed on an active ingredient basis, calculated on average market share over the three year period of FY 1990 - FY 1992, an individual product reregistration fee, and continuation of annual maintenance fees.

Provision of these fees will enable EPA to reduce its dependence upon outside contractors for science data reviews, to maintain in-house expertise during the critical decision-making years of the reregistration program, and to respond effectively to the new requirements of this legislation.

#### **NATIONAL PESTICIDE ADVISORY COMMITTEE**

The Administration also supports the creation in statute of a National Pesticide Advisory Committee. This should be a broadly representative committee comprised of 15 members serving

three year staggered terms. The Committee should meet at least twice a year to review progress in carrying out our pesticide laws and policies.

### III. NAS CHILDREN'S STUDY FOLLOW-UP INITIATIVE

We would now like to turn to a discussion of the administrative initiatives that are underway to address the recommendations of the recent NAS report, "Pesticides in the Diets of Infants and Children."

The NAS report recommended a number of changes in the regulation of food-use pesticides to provide a greater level of assurance that our children are protected from pesticide risks. Commissioned by Congress in 1988, the report examines how EPA regulates pesticides in foods, with special emphasis on the foods regularly eaten by infants and children. The recommendations cover all three of the basic elements of our traditional approach to evaluating food safety: toxicity testing, or the identification of the potential to cause harm; exposure analysis, or the determination of how much of a pesticide residue we are exposed to when we eat; and risk assessment, or the ways we combine and interpret the toxicity and exposure data to determine whether our foods are safe.

Not surprisingly, the Academy confirmed that there are age-related variations in susceptibility to the toxicity of environmental agents such as pesticides. For example, both anatomical and physiological differences are the basis for different rates of metabolism, respiration and growth. Because of these and other differences, the Academy recommended modifying current reproductive, developmental, and carcinogenicity testing

protocols and adding studies to test for pesticide neurotoxicity, immunotoxicity, and hormonal effects.

The Academy reaffirmed age-related differences in the amount of exposure to pesticide residues for infants and children. For their size, children consume more food than adults do, eat fewer types of foods, and drink more water. To address these differences, the Academy recommended more and better food consumption data targeting specific age groups from infancy through adolescence, more and better pesticide residue data on basic foods (raw agricultural commodities) and processed foods, standardized methods for reporting residue monitoring and maintaining residue data bases, and characterization of exposure from nondietary sources in assessing tolerances under FFDCA.

To better characterize exposure and risk, the Academy recommended use of a statistical procedure for determining potential distributions or ranges of pesticide exposure based on limited actual exposure data. This procedure, if supported by sufficient "real" data, could allow better assessment of subpopulations which may be at greater risk than is possible with current methods. The Academy also recommended considering all routes of exposure to a pesticide in assessing risk, combining exposure through the diet with environmental sources such as air, indoor surfaces, lawns, and pets, as well as combining exposures to pesticides with common toxic effects. Finally, where toxicity data are incomplete or there is evidence of frank developmental toxicity in animal studies, the Academy recommended use of an

additional uncertainty, or "safety" factor when defining acceptable exposure limits.

These recommendations, taken as a whole, present a great challenge in terms of higher standards for the quality, quantity, sensitivity, and scope of the data we use for evaluating risk. This is a challenge we are prepared to meet. We want to ensure that the decision making process for setting tolerances is based on health considerations, incorporating improved exposure estimates and better hazard characterization. We must not overlook the fact, however, that demands for more and better data development will also have important resource implications, for government agencies and the private sector. We must work to effect needed changes efficiently to minimize these burdens, while assuring that protective standards are maintained and enforced.

Efforts are well underway to assess and implement the Academy's recommendations where appropriate. We are ready to tackle the numerous issues. We have already accomplished a number of key tasks, and we will be initiating others in the near future.

#### **Organization**

The Office of Pesticide Programs (OPP) within EPA has the lead in organizing this initiative, with very significant participation from USDA and FDA. In addition, OPP has an array of outside participation in our NAS study work groups, including representatives of other HHS offices, Department of Commerce,

Department of Defense, state regulatory agencies, and the U.S. Census Bureau. It is evident from the sheer size of our task that we will need to elicit the help and cooperation of a wide variety of outside groups, and we have already met with organizations who have offered their support and assistance, particularly in the area of pesticide use reduction.

#### **Progress**

EPA, FDA, and USDA are committed to making real progress and expect to achieve tangible results within the coming year. While this initiative represents a new frontier for the federal government, we began work even in advance of the NAS report, with the goals of improving the science base for pesticide decisions very much in mind. The impetus of the NAS report and the Administration's commitment to reducing the risk of pesticide use imparted increased energy, tenacity, and enthusiasm to our efforts. Some of the relevant programs that are now in place, our actual accomplishments, short-term plans, and near-term goals are described below.

#### Toxicology

As part of the registration or reregistration of a pesticide, EPA requires a battery of toxicological tests to be performed. Registrants must submit a number of studies including acute, subchronic, and chronic toxicity studies; carcinogenicity (cancer or tumor causing effects), developmental toxicity (e.g., birth defects), and mutagenicity (genetic effects) studies; and

reproductive effects and metabolism studies. We also require data on environmental fate and ecological effects.

The NAS report recommended expanding the scope of this testing. Several of the recommendations in the report for additional or modified study requirements are in their final stages of development, while a few will require further work. EPA is reviewing and researching each new study suggestion. While it may be ideal to have as much data as possible from a purely scientific standpoint, we realize that in a regulatory setting, decisions must be made in a timely fashion based on the best available scientific information. Our decisions on new testing requirements will be subject to scientific peer review and open to comment by the general public.

Immune Function Testing. The NAS committee considered the human immune system to be among the more robust of systems in terms of resistance to pesticides or other chemical toxicity. In general, NAS concluded that EPA's current approach is sufficient. If abnormalities are found during histopathologic examination of the spleen, lymph nodes, thymus, and bone marrow, they suggest that more detailed and specific studies should be conducted on a case-by-case basis relevant to the types of effects initially seen in immune system tests.

EPA agrees with the committee's findings. We have prepared proposed protocols for immune system testing and will present these guidelines to a public meeting of EPA's Scientific Advisory Panel (SAP) this fall. EPA's guidelines are more comprehensive

than NAS recommended and consider a variety of endpoints, including changes in cell profile and thymus weights as well as histopathological changes. The guidelines will be finalized following SAP review.

Neurotoxicity Testing. In March 1991, EPA issued new and revised guidelines for conducting studies to determine the effects of pesticides on the nervous system. They include a description of how to assess the effects of pesticides on the developing nervous system both before and after birth. EPA also proposed requiring data for acute and subchronic neurotoxicity testing. Following the issuance of the guidelines, EPA required the development of such data for certain pesticides such as organophosphate and carbamates. Data call-ins (DCIs) were issued beginning in early 1991, and DCIs for over 66 chemicals or chemical cases have gone out to date. The NAS committee encouraged EPA to require neurotoxicity testing for all food-use pesticides as a general data requirement. This question will be presented for public review when we propose revised requirements for all pesticide regulatory testing. Current plans call for review of this proposed rule by the SAP and publication for public notice and comment in 1994.

Visual System Testing. The NAS committee recommended that a general guideline for visual system toxicity testing be established that can be modified and applied on a case-by-case basis. EPA has been working to design suitable protocols for sensory testing which will reliably predict visual system

toxicity and has developed testing guidelines which are in the final stages of internal review. These guidelines will also be presented to EPA's Scientific Advisory Panel in 1994 and finalized following SAP review.

Other NAS recommendations for added or modified toxicological studies will require more investigation into their feasibility and compatibility with our regulatory needs. These studies would include studies on age-related physiology, pharmacokinetics in immature animals, *in utero* exposures and cancer, and hormonal measurements.

#### Residue Data and Tolerance Setting

Use of Field Trial Data in Exposure Estimation. Results from multiple pesticide field trials are currently used by EPA in setting tolerances. The tolerance is often used in dietary exposure estimates for acute effects and is also the initial value used in chronic risk assessments. Tolerances facilitate enforcement of the use directions on registered products and will overestimate actual dietary exposure over a lifetime because they are set to cover maximum residue levels found in unpeeled, unwashed, uncooked commodities collected at the farm gate following treatments made at the maximum label rates and harvested at the minimum allowed interval following treatment. On the other hand, the tolerance value may, in some cases, underestimate acute exposure because it is based on composite samples that represent an average value for individual items collected.

The NAS report suggests that data from pesticide field trials be utilized to provide a basis for estimating potential maximum residue levels for acute effects and that more and better data be used for estimating dietary exposure for chronic or long term effects. We agree with these recommendations. EPA already uses field trial data as a basis for estimating maximum residue levels. It has also published for comment draft guidelines for the generation of better residue data to be used in both chronic and acute dietary risk assessments. These new guidelines will complement existing residue field trial guidelines and will document a more formal and uniform approach to assessing both short and long-term dietary health risks. Public comments have been solicited and EPA will finalize these guidelines in 1994, following SAP review.

Monitoring Pesticide Residues in Foods. The NAS committee emphasized the importance of obtaining more and better monitoring and processing data for use in estimating dietary exposure of children to pesticide residues. The Academy outlined a number of potential areas for improvement, including standardized reporting formats; the establishment of a national monitoring data base; market basket surveys designed around infants and children with an independent validation process; the institution of sampling strategies; and more sensitive analytical methods for detecting residues. The three agencies are examining these proposals carefully for their added value compared to current data

collection practices and are looking into other possible improvements.

While substantial changes in these areas are likely to be costly, important advances have already been made, and are ongoing. For example, significant progress has been made in recent years to standardize reporting of pesticide residue monitoring data. FDA's monitoring data reporting system has been adopted, to some extent, by many states and by USDA's Agricultural Marketing Service in its Pesticide Data Program. Recording of multiple residues when found in a single food sample is currently standard operating procedure in the FDA Pesticide Program, the USDA Agricultural Marketing Service's Pesticide Data Program, and the USDA Food Safety and Inspection Service's monitoring of meat and poultry. Since 1986, FDA has had a contract with Mississippi State University to compile state data into a data base. In 1989, EPA developed the Pesticide Residues Information System, which uses this state monitoring data base, as well as data generated by the National Food Processors Association, Agriculture Canada (now the Department of Agriculture and Food), and Scientific Certification Systems. The data base has been recently updated and is now available to the public.

In October, FDA will implement a statistically designed incidence level monitoring program for apples and rice. Both are listed in the NAS report as high consumption items for children. FDA will ensure that rice destined for baby food is included in

this program. Last year's statistically based incidence level program included pears, another food identified by NAS as a high-consumption food for children. Currently, FDA's "Total Diet Study" looks at eight subgroups of the population, including two children's age groups, 6 to 11 months, and 1-2 years. Soon, the study will be expanded to 14 subgroups with more groups for children.

#### Food Consumption

Dietary Surveys. One element of assessing dietary exposure to pesticides is a determination of how much and what types of food are consumed. EPA uses the computerized Dietary Risk Evaluation System (DRES) to estimate the amount of the pesticide in the daily diet, using national food consumption survey data from USDA. DRES allows us to assess the potential risks to a number of age-based population groups including infants and children; several different ethnic groups; and regional populations.

While DRES represents a significant advance over earlier methods of utilizing food consumption data, we agree with the NAS recommendation that more and better data are needed, especially on children in different age groups. Data in DRES currently are derived from USDA's 1977-78 Nationwide Food Consumption Survey (NFCS). Because of the apparent changes in America's eating habits since that time, and the relatively limited sample sizes for children in the 1977-78 NFCS, we need a more up-to-date data base.

We are evaluating several existing surveys, such as USDA's Continuing Survey of Food Intakes by Individuals (CSFII) and the Department of Health and Human Services' National Health and Nutrition Examination Survey (NHANES), which contains water consumption information. EPA is considering using one of these two surveys in the near term for an interim upgrade of DRES, although there are certain age groups for which sample sizes may not be fully adequate and NHANES excludes infants less than two months of age. USDA and EPA, along with HHS and the Bureau of the Census, are currently designing a special supplemental survey to acquire data adequate for EPA's purposes with respect to understanding the dietary patterns of infants and children. These data would provide better support for special findings with respect to children as part of the tolerance setting process described in the legislative portion of our testimony.

Additional future surveys will be designed to provide better data, but we need to explore whether a single survey design can simultaneously meet the needs of nutrition and food safety agencies, both of which need well-designed surveys. EPA will be working with USDA, FDA and other federal agencies on the design of future food consumption studies to help make sure that these studies provide the information needed for more precise estimates of risk for the general population, as well as infants and children.

Food Composition. EPA uses DRES to estimate food consumption. The foods reported are evaluated in terms of their

individual ingredients. For example, a chocolate chip cookie may be made up of flour, eggs, sugar, vegetable (soybean and/or cottonseed) oil, cocoa, whole milk, corn syrup, and molasses. This breakdown of foods is necessary because the pesticide residues in the foods as they are eaten are the sum total of residues in the individual components of the food. The NAS committee recommends that a simple, uniform method be developed for conversion of a product as consumed to its components in terms of raw agricultural commodities (RACs).

The Human Nutrition Information Service's (HNIS) Food Grouping System, which has been under development for some time, is envisioned as the means of providing a simple, uniform method for converting foods to RACs. This system will allow for standardized conversion. While HNIS is completing work on the Food Grouping System, EPA is developing an improved list of raw agricultural commodities so that all HNIS recipes can be standardized to the new DRES RAC list.

#### Risk Assessment

Additional Uncertainty Factor(s). The NAS committee recommended that an additional uncertainty factor of up to 10 be used when there is evidence of developmental toxicity following birth and/or when data from toxicity testing relative to children are incomplete.

Current EPA practice prefers to derive guidelines or benchmarks for chronic exposures from a complete, "ideal" set of toxicology studies. These studies include two or more chronic

studies in different species along with one or more acceptable studies which evaluate the potential for reproductive effects and two or more (prenatal) developmental studies in different species. The Agency usually applies the standard 100-fold uncertainty factor to the most appropriate toxicological endpoint identified in these studies. Unless the existing data base includes the "ideal" set, including information about risks for children, EPA will use an additional uncertainty factor of up to ten to accommodate for incomplete knowledge of the pesticide's toxicity potential. Our current methodology provides flexibility for application of uncertainty factors of lesser or greater magnitude, if the data warrant it. We will evaluate whether our standard practice should be further modified in light of the NAS recommendation.

Other Sources of Exposure. The NAS committee concluded that to properly evaluate potential pesticide risks, other avenues of exposure to the same pesticide should be included in an overall risk assessment. Presence of the pesticide in other foods, nondietary exposures, and water consumption should be considered. EPA will be working to develop a policy proposal which attempts to provide a consistent approach toward "allocating" allowable levels of exposure from various sources such as air, water, and food. Currently, in setting Maximum Contaminant Levels (MCLs) under the Safe Drinking Water Act, EPA generally allocates 20% of exposure to contaminants to drinking water.

Similarly, it is clear that people are exposed to multiple pesticides known to have common mechanisms of action. This issue is of concern because this could theoretically lead to the summing of risks from different pesticide exposures. However, it is a complex issue how to concurrently evaluate the toxicity of several pesticides that act via the same the mechanism. Further research will be required to develop these techniques, but EPA will take into account exposures to multiple pesticides acting via the same mechanism.

Use of the Benchmark Dose. EPA fully accepts the NAS committee's recommendation that we should explore the use of the benchmark dose approach for risk assessment applications involving infants and children. The benchmark dose concept has been developed as an alternative methodology for deriving quantitative measures of hazard and is argued to have several advantages over current methods. Work is underway on the feasibility of the use of benchmark doses as an integrated approach to cancer and noncancer risk assessment, with initial emphasis on the specific definitions, assumptions, decision points, and science policy required for its implementation in noncancer risk assessment. Potential applicability to specific subpopulations such as the young is being considered. EPA, the International Life Sciences Institute, and the American Industrial Health Council are sponsoring a public workshop at which the work done with respect to developmental toxicity will be discussed. In addition, OPP has acquired necessary computer

software and will be developing case studies during the next fiscal year.

Use of Probability Distribution Curves. EPA also agrees with the NAS recommendation to use probability distributions based upon actual data rather than simple summary statistics. This is in order to protect not just the average but also the more vulnerable in the population, including children. Distributions for food consumption and residue levels can be combined into composite exposure distribution curves. Current EPA practices for acute dietary exposure and risk assessment incorporate some features of this approach, and work is underway to upgrade the DRES to incorporate the NAS recommendations. Improvements to DRES will include increased capabilities for distribution analyses in the acute dietary assessment process, and potentially in the chronic assessment process. The NAS committee has agreed to provide us with the software it used in its case studies. As the committee noted, however, full utilization of this technique is predicated upon the acquisition of more and improved data on residues and food consumption.

#### Incident Monitoring

The Academy's report does not specifically mention pesticide incident monitoring, but the Administration believes that better incident information is essential for better protection of human health and the environment. As discussed briefly in the legislative section of our testimony, EPA is expanding its incident monitoring efforts and we are examining the role of HHS

surveillance programs as well. We need information on risks that may only become apparent after pesticide registration decisions, including useful and reliable data on poisonings, spills, wildlife kills, misuse, water resource contamination, and crop damage. Such data are indicators of program effectiveness and also provide us with the basis for post-registration remedial actions.

EPA is trying to build its capacity and is exploring the idea of a comprehensive incident monitoring system to gather and analyze post-registration exposure data. EPA's Incident Data System (IDS) received about 2,000 incident reports during 1992. By comparison, the American Association of Poison Control Centers surveillance system received 54,577 reports of pesticide exposure, 26,725 of which involved children under six years of age. While not all of these possible exposure reports were associated with adverse effects, we need to do more to enhance our incident data systems.

EPA created the IDS to record the pesticide incident information it receives. The first phase became operational in June 1992 and consists of core data files, tracking mechanisms and an on-line query capability. In the fifteen months it has been in existence, EPA has received about 2,900 incident reports, including 1,106 human incidents. IDS does not have the capacity to break this number down to determine how many incidents involve children. Information contained in IDS is available to the public.

Another EPA program is aimed at securing incident information from pesticide manufacturers. Under section 6(a)(2) of FIFRA, pesticide registrants must report to EPA any new information indicating that their products may cause unreasonable adverse effects. EPA has a team to flag such submitted data and facilitate expedited review so that the agency may take swift regulatory action if necessary. EPA is in the process of strengthening the FIFRA 6(a)(2) program. We plan to publish a final rule next spring specifying the types of information and data that must be reported to EPA.

Under cooperative enforcement agreements with EPA, states conduct more than 50,000 pesticide inspections for potential pesticide violations each year. EPA has begun developing a program, called the Pesticide Field Data Plan (PFDP), whereby field results from these inspections will be made available for use in future regulatory and non-regulatory activities. Information from the PFDP may also be entered into IDS as it is further developed.

#### IV. PESTICIDE USE REDUCTION

The Administration in June announced a dramatic shift in the government's approach to the use of pesticides. The centerpiece of this new approach is a commitment to the reduction of risks and a concomitant reduction in use of pesticides that raise risk concerns. This commitment means that our efforts will focus on reducing the overall risks from the use of pesticides through integrated pest management programs which lead to more sustainable agricultural production strategies and reductions in the use of pesticides.

Many of our legislative proposals provide regulatory mechanisms to reduce or eliminate risks from pesticides in a timely manner. The tolerance review process, label call-in, and phase out/phase down authorities, as well as improvements to the suspension and cancellation process, will all work to ensure decisive action to reduce or eliminate risks posed by specific pesticides. In addition, incentives for the development of new pest control measures will offer improved pest management tools for the future.

No amount of legislative direction can succeed, however, unless it is accompanied by corresponding changes at the user level. In the final analysis, it is the pesticide user who makes day-to-day pest management decisions that govern the introduction of pesticides into the environment. For legislative changes to have the desired effect at the field level, we need to take a systems approach to the reduction of risk which provides

agricultural producers with the knowledge and technologies needed to reduce the risks associated with pesticide use in the course of producing their crops. While EPA and FDA must retain a primary focus on regulatory action, they must also, in concert with USDA, work to create programs which provide production systems that prevent or mitigate the human health and environmental impacts of agricultural practices. The commitment to reducing pesticide risks and associated use will require changes not only in the ways that we regulate and register pesticides, but also in the programs we develop to collect and provide information and technology for agricultural producers and other pesticide users.

#### Regulation and Registration

Although all of EPA's pesticide regulatory activities now have risk reduction as a goal, current programs tend to focus on individual pesticides that have hit "risk triggers." In determining the appropriate regulatory response for a potentially risky pesticide, EPA evaluates substitute pest control options to ensure that regulatory decisions do not force users to resort to higher risk alternatives. Until recently, EPA has generally regulated pesticides using a chemical by chemical approach. Recent initiatives with USDA include implementing a "cluster" approach to examine all available pesticides for a particular crop, such as corn, the relative impact of those pesticides on economic activity, and alternative pest control options in light of the relative risks.

We are committed to making a concerted interagency effort to reduce pesticide risks and associated use. We will focus our efforts on uses, commodities, and products that present the greatest opportunities for risk reduction. We will take a close look at geographical areas and commodities that currently account for the largest total volume of pesticide use, those requiring the greatest pounds per acre of pesticide application, and those using the highest risk pesticides. We realize that a percentage targeting the reduction of volume of pesticides used should not be an endpoint. A 25% reduction in the use of a highly toxic pesticide may be preferable to an 80% reduction in use of a relatively safer pesticide. We will need to ensure that trade-offs in both agricultural and non-agricultural pesticide use are going in the right direction from a risk perspective.

We are developing a comprehensive program of regulatory and non-regulatory efforts designed to reduce the risk of high-risk pesticides by reducing their use. Our goal is threefold: 1) to discourage the use of higher risk products; 2) to provide incentives for the development and commercialization of safer products; and 3) to encourage the use of alternative control methods which decrease the reliance on toxic and persistent chemicals. A successful program must involve the full efforts of federal and state agencies, as well as the cooperation of the agricultural research community, growers and other pesticide users, pesticide producers, and food processors and distributors. We will work with all of these groups on high risk pesticides to

build support and encourage voluntary use reduction programs. The program will also involve independent agricultural consultants, public interest and environmental groups. EPA and USDA will continue to strengthen the partnerships created through the Agricultural Pollution Prevention Strategy, the Agriculture in Concert with the Environment program and the National IPM Forum.

Biological Control and Biological Pesticides. EPA intends to capitalize on and expand a number of projects that have been started in the past few years. One of the most visible and successful is its biologicals program. Biological pesticides comprise the single fastest growing segment of registration activity. Since the first biological pesticide, *Bacillus popilliae*, was registered in 1948, EPA has registered approximately 30 microbials and 50 biochemicals. Prior to 1985, registration of biologicals was rare, comprising at most 10% of all pesticides. In the past 2 years, 50% to 70% of all new pesticidal active ingredients registered have been biologicals.

Compared to conventional synthetic chemicals, biological pesticides represent a fundamentally different class of products. While they often demand a high level of management expertise to be successful, they are generally targeted to specific pests and therefore are likely to pose less risk to nontarget species. They hold the promise of enabling our nation's farmers to reduce the use of traditional synthetic chemicals. EPA is working to promote the development of biological products by reducing

unnecessary federal regulatory impediments. For example, EPA has established significantly reduced data requirements arranged in a tiered testing scheme that is tailored to the inherent characteristics of biologicals.

We are committed to encouraging the development, registration, and use of environmentally acceptable biological alternatives to more toxic and persistent conventional chemical pesticides. New applications for registration and experimental use permits for biologicals are given high priority at EPA. The processing time for registration of a new biological pesticide is generally 6 to 18 months, (compared to 2 to 3 years for a conventional pesticide). This translates into reduced time and cost to register biological pesticides. As mentioned earlier, we would support specific legislative mandates to provide further support to this regulatory approach and added incentives that will encourage private sector research and development efforts in biological controls.

Under the Federal Plant Pest Act and the Plant Quarantine Act, USDA issues permits for importation, interstate movement, and release of biocontrol agents in order to realize the beneficial potential of biocontrol and to ensure the safe introduction of biocontrol organisms. Biocontrol systems for management and regulatory control of major plant pest and weed problems will continue to be a primary focus for USDA in its research and implementation of IPM and area-wide pest management systems.

As part of a comprehensive strategy to encourage the use of reduced risk alternatives by lessening unnecessary regulatory burdens, EPA has an ongoing effort to identify pesticide active ingredients which are inherently low risk substances and may not require a high level of regulatory oversight. These pesticides may be appropriate for partial or complete exemption from FIFRA registration requirements.

One such project is the Pheromones Regulatory Relief Strategy. A pheromone is a chemical produced by an organism that modifies the behavior of other individuals of the same species. The use of these biochemicals to attract and trap, or disrupt the mating of insects has proven to be a successful pest management technology. Concerned that current regulations may impede pheromone research and development, EPA is considering plans for regulatory relief under FIFRA and FFDCA for pheromones contained in solid matrix dispensers (e.g., twist ties and plastic tapes) and plan to publish a proposal for regulatory relief by the end of this year. We are also exploring the appropriateness of reducing regulatory requirements for other types and formulations of pheromones.

Reduced-Risk Policy Initiative. As EPA examined its role in promoting safer pest control, we realized that our current regulatory program created barriers and provided few incentives for the development and use of safer pesticides. Now, both EPA and the private sector are responding to public interest in reducing pesticide-related risks and preventing pollution by the development and use of less toxic and less persistent pesticides.

The EPA Reduced-Risk Pesticide Policy Initiative was announced in the *Federal Register* in July 1992 and a public workshop was held the following October. Over 200 people attended the 2-day workshop and we received over 170 comments, ideas, and suggestions. Because of the overwhelming interest, we are planning another workshop which is scheduled for the second quarter of Fiscal Year 1994.

To develop a comprehensive reduced-risk policy, EPA's long term strategy will focus on three major themes derived from the first workshop: 1) developing reduced-risk criteria, 2) streamlining the registration process, and 3) initiating pesticide label reform and informational outreach. EPA's short-term plan is being implemented now. A Pesticide Regulation (PR) notice has been mailed to over 3,000 registrants, trade associations, environmental groups, and all those who attended the workshop. The PR notice announces that in setting priorities for the review of pesticide applications for new active ingredients, one of the factors EPA will consider is the opportunity for risk reduction. The notice provides general guidance to registrants on the types of supporting information they should provide if they believe their product will reduce risk.

As discussed in the legislative section of our testimony, we support legislative incentives to enhance reduced risk pesticide policies, including priority review and longer exclusive use data protection for these products.

Information and Technology Transfer

IPM and Demonstration Programs. The development and implementation of sound IPM programs constitute the primary mechanism by which pesticide risk and associated use can be reduced at the farm level. Applied research needs to be field-oriented so that producers have the tools necessary to mitigate current impacts, replace chemicals which present unacceptable risks, and maintain economical and sustainable production practices. USDA research and extension efforts to meet these goals must be intensified. USDA must also ensure that results are rigorously evaluated to ensure that they meet reduced risk goals and that they actually produce workable pest management tools that can be used by growers.

Both USDA and EPA have initiated innovative projects that will improve the ability of producers to move to more sustainable systems of production. USDA, through the efforts of several Departmental agencies, has initiated an "areawide" approach to the development of IPM programs. By focusing on a region's overall pest problems, the areawide initiative will develop solutions to a number of inter-related pest management problems in regions such as the apple producing region in the Pacific Northwest. By utilizing expertise from various agencies and disciplines, the project will develop a field-driven approach that can have immediate relevance to pressing environmental and production needs. This sort of project can provide a model for further collaborative and systems approaches to research and technology transfer.

For its part, EPA has entered into a cooperative agreement with the National Foundation for IPM Education to conduct pilot projects in agricultural pollution prevention. These pilots, with California processed tomato growers and New England apple growers, are voluntary efforts devised by the growers themselves to set and meet environmental goals.

In California, the tomato growers have set IPM implementation goals which will measure progress toward increasing adoption of environmentally sound growing practices. In New England, the apple growers are attempting to devise standardized documentation procedures for pesticide record-keeping and field monitoring data that can be used in establishing criteria to evaluate progress in maintaining healthy orchard ecosystems. In both cases, the projects will be used as examples for expanding agricultural pollution prevention initiatives to other crops and areas.

In order to fully meet its commitment to risk and associated use reduction, the Administration will have to increase its efforts in research and extension programs across a number of agencies. Clear goals will need to be established and careful evaluation of field level results will need to be undertaken. The examples listed above are only the beginnings of a task which has been started but has much more to accomplish.

Environmental Modeling and Analysis. Both EPA and USDA are researching and developing models to assess the impact of agricultural practices on the economic health of the food and feed producing industry and on the environment. An example of

the type of models that are being developed to assist in the regulatory decision process is EPA's Comprehensive Economic and Environmental Evaluation System (CEEPEs). CEEPEs is a modeling program which can be used to analyze economic and environmental outcomes based on various regulatory scenarios. By entering tillage type, soil, production or watershed area, county, region, and national information, we can generalize, using the model, potential impacts on such factors as grower income, environmental loading, water quality, and health and ecological risk. For example, analyses have been completed outlining the potential outcomes of a total ban on the pesticide atrazine, all related triazine herbicides, or restriction of atrazine use to postemergent weed control only. By the end of this year, we plan to complete model analyses of the impacts of alternate approaches atrazine use involving crop rotation, use of vegetation strips, and rate restrictions.

In summary, we believe that risk and associated use reduction efforts have tremendous potential in terms of positive effects on production agriculture. Farming is certainly resource intensive and we do not have all of the information that farmers need to maintain effective pest control and crop yields. We have mentioned some of the many things that are going on now. In the next few months we will be developing a framework and a long-term strategy for organizing and coordinating these efforts, setting priorities, and identifying additional efforts that need to be addressed. We will publish our strategy for the public to review and solicit their help and support in attaining these goals.



## V. CONCLUSION

This Administration is committed to making the 1990's a period of significant change in pesticide use and regulation. We are developing new partnerships to achieve pesticide use and risk reduction and undertaking new efforts to improve food safety and, in particular, provide additional assurance that our children are protected from pesticide risks. We are supporting comprehensive reform of both major pesticide laws to help us reach our public health and environmental protection goals. Our reform proposals will be prioritized by focusing major attention on tolerances for pesticide residues in food, beginning with an evaluation of all existing tolerances that may exceed the proposed new negligible risk standard.

While lengthy, our testimony today reflects just how complex these issues are, and the depth of our commitment to resolving them through a variety of initiatives on multiple fronts. We intend to do as much as possible within the constraints of existing law, but we also badly need to update both of our major pesticide statutes. We look forward to working with Congress in the coming months and would be pleased to respond to your questions.





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